Exhibit C

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Page 213
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                                    : SUPERIOR COURT OF
                                    : NEW JERSEY
 3
     IN RE:
                                    : LAW DIVISION -
                                    : ATLANTIC COUNTY
     PELVIC MESH/GYNECARE
 4
     LITIGATION
                                    : MASTER CASE 6341-10
 5
     (GENERAL, GROSS, WICKER)
                                    : CASE NO. 291 CT
 6
       CONFIDENTIAL-SUBJECT TO STIPULATION AND ORDER OF
 7
                        CONFIDENTIALITY
 8
 9
                  Tuesday, November 6, 2012
10
                           VOLUME II
11
12
               Transcript of the continued deposition of
13
     ANNE M. WEBER, M.D., M.S., called for examination in
     the above-captioned matter, said deposition taken
14
     pursuant to Superior Court Rules of Practice and
15
     Procedure by and before Kimberly A. Overwise, a
16
17
     Certified Realtime Reporter, Registered Professional
     Reporter, Certified Court Reporter, and Notary
18
19
     Public, at Mazie, Slater, Katz & Freeman, 103
     Eisenhower Parkway, 2nd Floor, Roseland, New Jersey,
20
21
     on the above date, beginning at 9:45 a.m.
22
23
                  GOLKOW TECHNOLOGIES, INC.
              877.370.3377 ph | 917.591.5672 fax
24
                       deps@golkow.com
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1 2 3 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	MAZIE SLATER KATZ & FREEMAN, LLC BY: ADAM M. SLATER, ESQ. 103 Eisenhower Parkway, 2nd Floor Roseland, NJ 07068 973-228-9898 aslater@mskf.net Counsel for Plaintiffs BERNSTEIN LIEBHARD LLP BY: JEFFREY S. GRAND, ESQ. 10 E. 40th Street, 22nd Floor New York, NY 10016 212-779-1414 grand@bernlieb.com Counsel for Plaintiffs BUTLER, SNOW, O'MARA, STEVENS & CANNADA, PLLC BY: CHRISTY D. JONES, ESQ. 1020 Highland Colony Parkway, Suite 1400 Ridgeland, MS 39157 601-948-5711 christy.jones@butlersnow.com Counsel for Johnson & Johnson and Ethicon BUTLER, SNOW, O'MARA, STEVENS & CANNADA, PLLC BY: NILS B. (BURT) SNELL, ESQ. 500 Office Center Drive, Suite 400 Fort Washington, PA 19034 267-513-1884 burt.snell@butlersnow.com Counsel for Johnson & Johnson and Ethicon SILLS CUMMIS & GROSS, P.C. BY: WILLIAM R. STUART, ESQ. One Riverfront Plaza Newark, NJ 07102 973-643-0700 wstuart@sillscummis.com Counsel for Caldera Medical, Inc., and Synovis	Page 214	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	I N D E X WITNESS: Page ANNE M. WEBER, M.D., M.S. By Ms. Jones	Page 216
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	APPEARANCES VIA PHONE AND STREAM: KLINE & SPECTER, P.C. BY: ROGER CAMERON, ESQ. 1525 Locust Street, 19th Floor Philadelphia, PA 19102 215-772-1000 roger.cameron@KlineSpecter.com Counsel for Plaintiffs	Page 215	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	NONE Question Marked	Page 217

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11 BY MS. JONES: 12 Q Let me clarify. I understand you may 13 review some additional depositions or documents, but 14 have you requested, for example, any materials on 15 either of those patients that you wish to review 16 that you've not yet had an opportunity to review? 17 A No. 18 Q Have you requested an opportunity to 19 examine either of those women? 20 A No. 21 Q Have you requested an opportunity to visit 22 with either of those women?				
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13 review some additional depositions or documents, but 14 have you requested, for example, any materials on 15 either of those patients that you wish to review 16 that you've not yet had an opportunity to review? 17 A No. 18 Q Have you requested an opportunity to 19 examine either of those women? 20 A No. 21 Q Have you requested an opportunity to visit 22 with either of those women?				
14 have you requested, for example, any materials on 15 either of those patients that you wish to review 16 that you've not yet had an opportunity to review? 17 A No. 18 Q Have you requested an opportunity to 19 examine either of those women? 20 A No. 21 Q Have you requested an opportunity to visit 22 with either of those women?				
15 either of those patients that you wish to review 16 that you've not yet had an opportunity to review? 17 A No. 18 Q Have you requested an opportunity to 19 examine either of those women? 20 A No. 21 Q Have you requested an opportunity to visit 22 with either of those women?				·
16 that you've not yet had an opportunity to review? 17 A No. 18 Q Have you requested an opportunity to 19 examine either of those women? 20 A No. 21 Q Have you requested an opportunity to visit 22 with either of those women?			15	
17 A No. 18 Q Have you requested an opportunity to 19 examine either of those women? 20 A No. 21 Q Have you requested an opportunity to visit 22 with either of those women?			16	
18 Q Have you requested an opportunity to 19 examine either of those women? 20 A No. 21 Q Have you requested an opportunity to visit 22 with either of those women?				
19 examine either of those women? 20 A No. 21 Q Have you requested an opportunity to visit 22 with either of those women?				, , , , , , , , , , , , , , , , , , , ,
21 Q Have you requested an opportunity to visit 22 with either of those women?	19			
22 with either of those women?				
	23		23	A No.
,	1/4		24	O I take it that you are comfortable
23 arriving at your opinions with respect to those	25		24 25	Q I take it that you are comfortable arriving at your opinions with respect to those

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Page 222
                                                                                                             Page 224
    women based upon the contents of the medical records
                                                           1
                                                               misbranded in any way?
    and the depositions that you've reviewed?
2
                                                           2
                                                                          MR. SLATER: To her knowledge?
       A And the reports.
                                                           3
3
                                                                          THE WITNESS: Not to my knowledge.
4
       Q And what reports?
                                                           4
                                                               BY MS. JONES:
5
       A The reports from the people who have
                                                           5
                                                                      The FDA did clear Gynemesh® PS, did it
    examined them.
                                                           6
6
                                                               not?
7
       Q Those who have examined them specifically
                                                           7
                                                                       Yes, it did.
                                                                   Α
8
    for purposes of this litigation?
                                                           8
                                                                       That was in 2002?
                                                                   0
9
       A Yes.
                                                           9
                                                                   Α
                                                                      Yes.
       Q Do you have any criticisms of the treating
10
                                                           10
                                                                   Q
                                                                       The mesh in Prolift® is identical to that
11
    surgeons or doctors who implanted the Prolift®s in
                                                           11
                                                               mesh?
    either Ms. Gross or Ms. Wicker?
12
                                                           12
                                                                      Yes. Excuse me. The mesh in Prolift® was
13
                                                           13
                                                               cut by a different method, it was not identical.
                                                                      I'm sorry. It was not what?
14
           Do you believe and is it your opinion that
                                                           14
    each of those women was an appropriate candidate for
                                                                   A It was not identical.
15
                                                           15
    the use of Prolift®?
                                                                      It was in a different shape; correct?
16
                                                           16
                                                                   Q
       A I do not agree.
                                                           17
                                                                       It was cut by a different method.
17
                                                                   Α
       Q Well, let me see if I can separate these
18
                                                           18
                                                                   Q
                                                                       It was also in a different shape, was it
    out. Is it your judgment that it is a breach of the
19
                                                           19
                                                               not?
20
    standard of care for a doctor to use Prolift® in any
                                                           20
                                                                       Correct, it was in a different shape.
                                                                   Α
21
    woman?
                                                           21
                                                                       And Gynemesh® PS was modified and cut by
22
       A I wouldn't call it a breach of the
                                                           22
                                                               surgeons in order to use it transvaginally, was it
23
    standard of care. I would call it a deception on
                                                           23
                                                               not?
24
    the part of Ethicon when they illegally marketed the
                                                           24
                                                                   Α
                                                                       Correct.
    Prolift® and did not notify physicians and patients
25
                                                           25
                                                                       Mesh has been used and cut to be used in
                                                                   Q
                                                  Page 223
                                                                                                             Page 225
    that was the case. Physicians were assuming they
                                                           1
                                                               transvaginal surgeries since the 1990s, has it not?
1
                                                           2
2
    were using a properly FDA-cleared device and that
                                                                          MR. SLATER: You're talking mesh in
3
                                                           3
    was untrue.
                                                               general; right?
4
               MS. JONES: Move to strike as
                                                            4
                                                                          MS. JONES: Uh-huh.
5
    nonresponsive.
                                                           5
                                                                          THE WITNESS: Correct.
                                                           6
6
    BY MS. JONES:
                                                               BY MS. JONES:
7
        O Doctor, in terms of whether or not the
                                                                   Q And that mesh in general was cut and used
                                                           7
8
    device was legally marketed, are you aware of the
                                                           8
                                                               to be used transvaginally by surgeons without FDA
    guidances that recognize that certain devices do not
                                                           9
                                                               clearance for use in that manner; correct?
    require 510(k) clearance prior to marketing?
                                                           10
                                                                   A That's an entirely different situation.
10
11
        A I am aware.
                                                               Off-label use by physicians is allowable. Illegal
                                                           11
                                                               marketing by a company is not.
12
        O Has the FDA ever begun, to your knowledge,
                                                           12
    any type of enforcement proceedings against Ethicon
13
                                                           13
                                                                          MS. JONES: Let's just move to strike
    with respect to Prolift®?
                                                               as nonresponsive.
14
                                                           14
15
        A The FDA informed Ethicon that it could not
                                                           15
                                                               BY MS. JONES:
    market Prolift® until the clearance process was
                                                                   Q Can you answer my question, Doctor?
16
                                                           16
    completed, and Ethicon did that anyway.
                                                                          MS. JONES: Do you want to read back
                                                           17
17
18
              MS. JONES: Move to strike as
                                                           18
                                                               my question.
                                                                          MR. SLATER: She probably thinks she
19
    nonresponsive.
                                                           19
                                                           20
                                                               did answer the question, as I do.
20
    BY MS. JONES:
                                                                          You understand when she moves to
21
        Q My question, Doctor, was: Has the FDA
                                                           21
    ever initiated any enforcement proceedings against
22
                                                           22
                                                               strike, she's preserving her rights for the future.
    Ethicon with respect to the marketing of Prolift®?
                                                               It doesn't mean that your testimony is actually
23
                                                           23
                                                               going to be stricken because I'm obviously going to
24
        A No.
                                                           24
           Has the FDA ever declared Prolift®
25
                                                           25
                                                               oppose those motions. I just want you to know
        Q
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Page 226 Page 228 procedurally what she's doing. She's just 1 1 Yes. 2 preserving her rights. It's perfectly fine to move 2 You use tools when you do abdominal 3 surgery, do you not? 3 to strike. 4 THE WITNESS: Okay. Could you repeat 4 A Yes. 5 Q You use tools when you do any type of 5 the question, please? 6 (The court reporter read the record 6 Prolift® surgery, don't you? 7 as follows: 7 Α Yes. 8 8 "OUESTION: And that mesh in general 0 In terms of --9 was cut and used to be used transvaginally by 9 A I'd like to expand on that, if I may. You 10 surgeons without FDA clearance for use in that 10 use tools that the hospital buys and the surgeon may 11 manner; correct?") 11 request that are also used for other procedures. The tools in the Prolift® procedure were developed 12 THE WITNESS: Correct. I'd like to 12 for use for the Prolift® procedure and only the 13 expand on that. 13 14 MR. SLATER: You can. 14 Prolift® procedure. Q Those tools were developed by surgeons, 15 THE WITNESS: The off-label use by 15 weren't they? 16 physicians of a material or a drug is allowable. 16 Illegal marketing of a commercial product without A No. They were developed by Ethicon. 17 17 18 FDA clearance is not. 18 Q You don't think that they were developed 19 BY MS. JONES: 19 working with surgeons? 20 Q Would you identify for me one place, 20 They were developed working with surgeons. Doctor, just one place, where the FDA has ever 21 And that surgeons use those tools? 21 suggested that Ethicon illegally marketed Prolift®? MR. SLATER: Is that a question? 22 22 A In the letters -- in the process -- in the 23 23 MS. JONES: That is a question. 24 interaction between FDA and Ethicon, the letter 24 THE WITNESS: They only use those stated you may not market this device while this tools because Prolift® is made available as a kit. 25 25 Page 227 Page 229 process of clearance is ongoing. 1 BY MS. JONES: 1 2 O Have you ever spoken with anyone at the 2 Those tools were used by surgeons before 3 FDA about that? 3 it was marketed as a kit, were they not? 4 A No. 4 Α No. 5 Q Have you ever seen, Doctor, anywhere in 5 Q Never? 6 writing anyplace where the FDA said we consider that 6 Α No. 7 Ethicon illegally marketed the device? 7 0 That's your testimony? A FDA determined, when they finally realized 8 8 Yes, it is. Α 9 Prolift® was on the market, that it required a 9 Q Have you ever used any of the Prolift® 10 separate application for clearance. 10 tools? MS. JONES: Move to strike as 11 11 Α No. 12 Q Prior to being engaged in this litigation, 12 nonresponsive. did you ever see any of those Prolift® tools? 13 BY MS. JONES: 13 Q My question, Doctor, was: Have you ever 14 14 A No. 15 seen anyplace where the FDA said specifically we 15 0 If we go back to your testimony with consider that Prolift® was illegally marketed? respect to Ms. Gross and Ms. Wicker, am I correct 16 16 MR. SLATER: You mean where those that you testified that you have no criticisms of 17 17 18 exact words were used? 18 the implanting surgeons? MS. JONES: That's exactly what I'm 19 The surgeons followed the standard 19 20 20 procedure of Prolift® implantation. My criticism is asking. of the Prolift® procedure and mesh implantation. 21 THE WITNESS: No. 21 O My guestion, Doctor, was as follows: Do 22 BY MS. JONES: 22 Q When surgeons began using mesh for you have any criticism whatsoever of the doctors who 23 23 transvaginal surgery in the 1990s, they used tools chose to use Prolift® in Ms. Gross and Ms. Wicker? 24 24 25 to place that mesh, did they not? 25 A No, I do not.

			7
	Page 230		Page 232
1	Q If we go back to the appropriate	1	Q Ulceration?
2	treatments for prolapse, I think you identified	2	A Yes.
3	three different classes of treatment, if you will.	3	Q Bleeding?
4	One is observational, just watching, if the patient	4	A Very uncommonly.
5	seems to be asymptomatic; correct?	5	Q And then if you're going to look at the
6	A Technically observation is not a form of	6	surgical treatments or therapies for prolapse, you
7	treatment.	7	have vaginal approaches, abdominal approaches,
8	Q If a woman has prolapse but seems to be	8	laparoscopic approaches, and robotic approaches;
9	asymptomatic, is it appropriate to observe and delay	9	correct?
10	any treatment?	10	A Laparoscopic approaches are abdominal
11	A Yes.	11	approaches. Robotic approaches are a subset of
12	Q Other therapies that are available would	12	laparoscopic approaches.
13	be exercises, as we've discussed, correct	13	Q Have you ever done laparoscopic surgery
14	A Yes.	14	for prolapse?
15	Q pelvic floor exercises? And the use of	15	A No.
16	pessaries; correct?	16	Q Have you ever done robotic surgery for
17	A Correct. And also behavioral and	17	prolapse?
18	lifestyle changes.	18	A I am going to correct that last statement.
19	Q In terms of pessaries, the pessaries are	19	I have performed paravaginal repairs
20	not suitable for treatment for every woman's	20	laparoscopically.
21	prolapse, are they?	21	Q On how many occasions?
22	A No, they are not.	22	A Perhaps 20 to 30.
23	Q And, indeed, pessaries may be difficult	23	Q Have you ever performed robotic surgery?
24	for some women to use; is that right?	24	A No.
25	A That is correct.	25	Q If one is evaluating the surgical
23	A That is correct.	23	Q If one is evaluating the surgical
	D 224		p. 222
	Page 231		Page 233
1	Q Oftentimes it may be that a woman has to	1	treatment for prolapse, one of the considerations is
2	visit her doctor three or four times a year in order	2	the type and severity of the prolapse that the woman
3	to have the pessary removed and cleaned and to	3	has?
4	consult with a doctor; correct?	4	A Yes.
5	A Correct.	5	Q The surgeon's training and experience?
6	Q Pessaries generally have to be removed	6	A Yes.
7	before sexual intercourse; correct?	7	Q The patient's preference for the type of
8	A No.	8	surgery after consultation with the physician?
9	Q There are those who recommend removal	9	A Yes.
10	before sexual intercourse, do they not?	10	Q And obviously the desired outcome;
11	A Are you speaking of physicians?	11	correct?
12	Q Yes.	12	A Yes.
13	A I can't speak to what all other physicians	13	Q For example, one of the surgeries that can
14	would recommend.	14	be performed for prolapse is obliterative surgery
15		15	that closes the vagina; correct?
	Q Have you seen it reported in the	13	
16	Q Have you seen it reported in the literature that one of the issues with the pessary	16	A Correct.
16	literature that one of the issues with the pessary	16	A Correct. Q And that would obviously be appropriate generally only for those who don't seek to have
16 17	literature that one of the issues with the pessary use is that it should be generally removed for	16 17	A Correct. Q And that would obviously be appropriate
16 17 18	literature that one of the issues with the pessary use is that it should be generally removed for sexual intercourse?	16 17 18	A Correct. Q And that would obviously be appropriate generally only for those who don't seek to have
16 17 18 19	literature that one of the issues with the pessary use is that it should be generally removed for sexual intercourse? A No.	16 17 18 19	A Correct. Q And that would obviously be appropriate generally only for those who don't seek to have intercourse in the future?
16 17 18 19 20 21	literature that one of the issues with the pessary use is that it should be generally removed for sexual intercourse? A No. Q Have you seen it reported in the literature that pessaries may be associated with	16 17 18 19 20 21	A Correct. Q And that would obviously be appropriate generally only for those who don't seek to have intercourse in the future? A Correct. Q When surgeons perform the surgeries, they
16 17 18 19 20 21 22	literature that one of the issues with the pessary use is that it should be generally removed for sexual intercourse? A No. Q Have you seen it reported in the	16 17 18 19 20 21 22	A Correct. Q And that would obviously be appropriate generally only for those who don't seek to have intercourse in the future? A Correct. Q When surgeons perform the surgeries, they often choose different techniques in performing the
16 17 18 19 20 21	literature that one of the issues with the pessary use is that it should be generally removed for sexual intercourse? A No. Q Have you seen it reported in the literature that pessaries may be associated with vaginal discharge? A Yes.	16 17 18 19 20 21	A Correct. Q And that would obviously be appropriate generally only for those who don't seek to have intercourse in the future? A Correct. Q When surgeons perform the surgeries, they often choose different techniques in performing the same surgeries, do they not?
16 17 18 19 20 21 22 23	literature that one of the issues with the pessary use is that it should be generally removed for sexual intercourse? A No. Q Have you seen it reported in the literature that pessaries may be associated with vaginal discharge? A Yes.	16 17 18 19 20 21 22 23	A Correct. Q And that would obviously be appropriate generally only for those who don't seek to have intercourse in the future? A Correct. Q When surgeons perform the surgeries, they often choose different techniques in performing the

Page 234 THE WITNESS: There are standard techniques of performing surgeries that surgeons may vary. BY MS. JONES: O And the surgeons vary based upon either different approaches and what they feel comfortable with or what they find to be satisfactory? A Correct.

- Q And as surgeons they may vary approaches in the sense of being innovative in order to provide better care to their patients?
- A That is a complicated answer because the line between innovation and experimentation is not black and white.
- Q Well, innovative approaches over time have led to better healthcare in general, have they not?
 - A No, I wouldn't agree with that in general.
- 18 Q Would you agree that all surgeries have 19 risks?
- 20 A Yes.

- Q That even in the absolute best of hands a surgeon that there are complications that may not be avoided?
- 24 A Yes.
- 25 Q If we talk about Ms. Gross, Ms. Gross had

determined that she needed an apical prolapse procedure, I would have considered an iliococcygeal muscle repair, possibly a uterosacral ligament suspension; and if I decided she needed it, which would probably be an intraoperative decision, an enterocele repair.

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- Q How would you have counseled Ms. Gross in advance of the surgery in terms of what her options for treatment were?
- A As we discussed, I would go over behavioral and lifestyle changes, pelvic muscle exercises, pessary use, and surgery.
- Q And do you understand that all of those were discussed with Ms. Gross?
- A My recollection from the records is that a pessary was discussed. I don't recall the behavioral and lifestyle changes and exercises.
- Q Do you recall that Ms. Gross was not interested in a pessary?
- A I recall that in the discussion with her physician he was not enthusiastic it would be a good solution for her. And in her experience she also preferred not to choose a pessary.
- Q What would you have discussed with Ms. Gross about her surgical options?

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had prior surgeries before she had the surgery involving Prolift®, had she not?

- A Correct.
- Q Had some recurrent prolapse?
- A She did not have recurrent prolapse.
 - Q She'd had a hysterectomy before?
- A Correct.
- Q That's one of the issues that you consider when you determine what surgery would be appropriate?
 - A I don't understand your question.
- Q Is it appropriate to consider what prior surgeries a patient has had before you determine what surgery to perform to correct the prolapse?
- A Of course, that's part of the patient's history. I don't know that that necessarily modifies the surgical approach to her current prolapse problem.
- Q Let me just ask you this: What options would you have considered as Ms. Gross' surgeon to correct her problems in 2006?
- A Based on my understanding of her condition at that time, with a Grade 3 to 4 rectocele and an enterocele above that, I would have considered a rectocele repair, a posterior colporrhaphy. If I

A I would have discussed the procedures I named before and that at least part of the decision would be based on the intraoperative findings.

Q And what would you have told her were the complications associated with the surgery?

A As we discussed yesterday, the general risks of any surgery: Bleeding, infection, risk of anesthesia, complications that aren't directly related to the surgical site but occur postoperatively, like blood clots, pneumonia.

And then specific to the surgery, after surgery pain with intercourse, voiding dysfunction. I would mention the risk of ureteral injury since a possibility would be uterosacral ligament suspension, other organ injury that may need other surgery to repair it. That's all I can think of at the moment.

- Q Would you discuss with her risk of damage to the pudendal nerve?
- A Nerve damage. I consider in the organ tissue damage category nerve damage. I would only specifically mention that if I were considering a sacrospinous ligament fixation. O What would you have told her about the
 - Q What would you have told her about the possibility of recurrence?

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A That these operations aren't perfect, we can't obviously guarantee 100 percent success, and that there's a possibility that her problem could come back.

- Q And, in fact, about 30 percent of all prolapse surgeries are for recurrence, aren't they?
 - A I don't think that's a reliable number.
- O That's certainly --

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- 9 A That's from one study.
- 10 Q That number's certainly been reported, has 11 it not?
 - A It's been reported to death.
 - Q And there have been different studies which have reported recurrence rates as high and in excess of 50 percent; correct?
 - A Recurrence, again, is a definition that's undergone modification. At a time in the past when anatomic outcomes were the focus, patients were labeled as having recurrent prolapse when it passed a certain arbitrary point in the POP-Q system. Many of those women are asymptomatic, they don't need subsequent surgery, they go on about their lives.
 - Q My question was, Doctor: Rates of recurrence in excess of 50 percent have been reported, have they not?

1 products?

- A Not specifically, no.
- Q Can you identify any transvaginal mesh product that has more published clinical data than Prolift®?

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- A I think the relevant point is that there was no data on Prolift® at launch.
 - MS. JONES: Move to strike as
- 9 nonresponsive.
- 10 BY MS. JONES:
- 11 Q My question, Doctor, was: Can you identify any transvaginal mesh product for whom 12 there is more published clinical data than on 13 14 Prolift®?
 - This is 2012. It's an entirely different situation. And Ethicon pulled Prolift® off the market in the face of all this data because it was not safe and not effective.
 - MS. JONES: Move to strike as nonresponsive.
- 21 BY MS. JONES:
- 22 Q My question for the third time, Doctor, is: Can you identify a single transvaginal mesh 23 24 product for which there is more published clinical data than Prolift®? 25

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- A Correct.
- Q Those have been reported out of the Cleveland Clinic; correct?
 - A Correct.
- Q Those were reported out of the Cleveland Clinic when you were there; correct?
- A It was certainly a study I co-authored. I don't remember exactly when that was published, if I had left the Cleveland Clinic by then.
- Q But the patients in the study, patients were treated and the study was conducted while you were at the Cleveland Clinic?
 - A Correct.
- Q You are aware, are you not, that the FDA premarket notification process prior to 2005 did not require original clinical studies to support the clearance of surgical mesh; correct?
 - A Correct.
- Q In the course of looking at and reviewing these records, have you looked at any clinical data that was used to support the clearance of the AMS products Apogee® or Perigee®?
 - A Not specifically, no.
- Q Had you ever looked at any clinical data or ever seen any clinical data on those two

Α No.

- Can you identify other than Prolift® any transvaginal mesh product for whom there is more published data than Gynemesh® PS?
 - Α No.
- Q Have you reviewed, Doctor, any of the preclinical bench or animal studies done on the Prolene® PS or the Prolene® mesh?
 - The Gynemesh® PS mesh?
- 10 Q Or the Gynemesh® PS mesh.
 - Yes. Α
- 12 What studies have you reviewed?
- The animal studies in a rat model looking 13 at mesh implantation in an abdominal location for 14 15 short-term histologic changes.
 - Q I think I asked you this yesterday. But I'm not certain. Have you yourself actually ever performed any animal studies?
 - A I have assisted the fellows in their work with Dr. Moalli at the University of Pittsburgh in her studies of -- in her animal studies. And at the Cleveland Clinic I supervised the fellows in the performance of their research with animals.
- 24 Q Have you ever actually implanted mesh in 25 an animal?

1	Page 242 A No.	1	Page 244 A Yes.
2	Q Have you ever actually taken mesh out of	2	Q Ever had any difficulties with use of
3	an animal and examined it pathologically?	3	those sutures?
4	A I have not taken mesh out of an animal. I	4	A Difficulties like what?
5	have examined it pathologically.	5	Q I'm asking you, Doctor.
6	Q The tissues from the animal?	6	MR. SLATER: She's asking you to
7	A Yes.	7	define what you mean by "difficulties." It's a
8	Q Have you ever published on any of those	8	pretty ambiguous term, which I object to.
9	animal review studies?	9	BY MS. JONES:
10	A They have been published. I am not a	10	Q You can't answer that question, Doctor?
11	co-author.	11	MR. SLATER: Can you refine what you
12	Q Doctor, have you ever performed any	12	mean by "difficulties"?
13	studies to evaluate the foreign body response to any	13	MS. JONES: I'm asking the doctor
14	mesh?	14	whether she can answer the question.
15	A No.	15	MR. SLATER: She already asked you to
16	Q What is your understanding of the size of	16	define the term so I don't understand why you won't
17	a microphage?	17	do it.
18	A I'm sorry?	18	MS. JONES: Because I'm asking the
19	Q Do you know what the size of a microphage	19	questions, counsel.
20	is?	20	MR. SLATER: Okay. But she's already
21	MR. SLATER: A macrophage?	21	asked you to refine what you mean. So normally when
22	THE WITNESS: Macrophage? Macrophage	22	you're taking a deposition and the witness says I
23	is what you're saying?	23	don't know what you mean, you refine the question.
24	BY MS. JONES:	24	MS. JONES: This is the first
25	Q Yes, yes.	25	deposition I've ever taken, Doctor I mean,
	Page 243		Page 245
1			
	A Macrophage is in the range of 10 to	1	
1 2	A Macrophage is in the range of 10 to 20 microns.	1 2	counsel.
2	20 microns.	1 2 3	counsel. MR. SLATER: If you're going to start
2		2	counsel. MR. SLATER: If you're going to start calling me Dr. Slater, okay, you're not going to be
2	20 microns. Q Do you know what the size of a leukocyte	2	counsel. MR. SLATER: If you're going to start
2 3 4	20 microns. Q Do you know what the size of a leukocyte is? A Macrophages are in the family of leukocytes, so, yes, 10 to 20 microns.	2 3 4	counsel. MR. SLATER: If you're going to start calling me Dr. Slater, okay, you're not going to be the first one. It's a big step up for me. Wow. BY MS. JONES: Q Have you ever filed an adverse experience
2 3 4 5 6 7	20 microns. Q Do you know what the size of a leukocyte is? A Macrophages are in the family of leukocytes, so, yes, 10 to 20 microns. Q Have you ever seen any criticism by the	2 3 4 5 6 7	counsel. MR. SLATER: If you're going to start calling me Dr. Slater, okay, you're not going to be the first one. It's a big step up for me. Wow. BY MS. JONES: Q Have you ever filed an adverse experience report with respect to polypropylene sutures?
2 3 4 5 6 7 8	20 microns. Q Do you know what the size of a leukocyte is? A Macrophages are in the family of leukocytes, so, yes, 10 to 20 microns. Q Have you ever seen any criticism by the FDA of the pore size of the Gynemesh® PS or the	2 3 4 5 6 7 8	counsel. MR. SLATER: If you're going to start calling me Dr. Slater, okay, you're not going to be the first one. It's a big step up for me. Wow. BY MS. JONES: Q Have you ever filed an adverse experience report with respect to polypropylene sutures? A No.
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Page 246 Q My question, Doctor, was whether or not you had actually seen mesh that showed any evidence of degradation. A I believe I answered your question. O You've held mesh that shows evidence of degradation?

- A You didn't ask me if I held it.
- Q Let's see if we can get on the same wavelength.

MR. SLATER: Whatever you do, don't get on the same wavelength.

12 BY MS. JONES:

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- Q I'm asking you, Doctor, whether or not you have held in your hands any polypropylene mesh of which you decided or could discern any evidence of degradation.
 - A No.
- Q Have you ever had a patient who had a failure of mesh that you attributed to degradation?
- A I can't say -- I can't say. I can't say no for sure. Patients experience failure and it's possible that it's due to suture breakage, which would be due to suture degradation.
- O All right. Maybe we miscommunicated. I 25 was asking you about the mesh itself this time.

retrospective chart reviews. I don't recall seeing any prospective research.

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- Q Do you recall reviewing any biomaterials literature at that time with respect to the characteristics of polypropylene?
 - A I may have. I can't say for sure.
- Do you remember reviewing any literature with respect to the historical use of polypropylene in the body?
 - A I would expect so.
- Q Well, can you tell me as you sit here today when polypropylene was first used in the body?
 - A I believe it was in the '50s or '60s.
- O Do you know when polypropylene mesh was first used in the body?
 - A I believe in that same time, '50s or '60s.
- O As you sit here today, Doctor, can you identify any alternative mesh product that you believe is a better product for use to treat prolapse than Gynemesh® PS?
- A I don't believe mesh of any type in the polypropylene family is an appropriate choice for transvaginal mesh implantation.
- Q Let me ask the question a little bit differently. Can you identify for me any type of

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MR. SLATER: What's the question? She must have misunderstood.

MS. JONES: I asked her whether or not she had ever had a failure of mesh in a patient that she attributed to degradation.

THE WITNESS: No.

BY MS. JONES:

- Q Prior to becoming or being retained as an expert in this litigation, is it fair to say that you had not previously reviewed the literature on polypropylene?
- A In my experience as the program director for the pelvic floor disorders network, we were considering the design of a trial using mesh. At that time I would have reviewed the literature to understand what had been done with mesh products and what other research was needed.
- Q What can you remember about your review of the literature at that time specifically as it relates to polypropylene mesh?
 - A The literature was lacking.
- Q What can you remember about your review of 22 23 the literature at that time with respect to
- polypropylene mesh? 24
 - A There may have been case series and

mesh that you believe is appropriate for use transvaginally?

- A Based on my background and my study, my conclusion is that any mesh placed transvaginally for prolapse exceeds -- the risks far exceed the benefit.
- O Am I correct then, Doctor, that you, as you sit here today, cannot identify for us an alternative mesh to Prolift® for use transvaginally to repair prolapse?
- A You're suggesting an alternative is necessary. I don't agree with that.
- Q I'm just asking you, Doctor, whether or not you can identify one. 14

MR. SLATER: Well, let me just ask what the question means. She just told you she doesn't think any of the meshes should be used. So when you say can you identify one, are you asking her to just list them? MS. JONES: Could we not have

speaking objections?

MR. SLATER: Well, I object to the 22

form. It's incredibly ambiguous, the question. 23

24 Could you rephrase it? 25

MS. JONES: How about let me conduct

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this and you just say objection, as I have done at your depositions, and we'll be in good shape.

MR. SLATER: Well, you went a little past the word "objection," with all due respect, so I think the question is extremely confusing and ambiguous.

BY MS. JONES:

- Q I'm asking you, Doctor, this question: You have told us that you do not consider any mesh to be appropriately used for the transvaginal treatment of prolapse; is that correct?
- A I believe I said polypropylene mesh or mesh in the polypropylene family.
- Q All right. That's what I thought you said. So can you tell me then of any mesh that can be appropriately used transvaginally?
 - A I don't believe such a product exists.
- Q So it's fair to say that while you're saying polypropylene mesh should not be used, that you're not suggesting that there is a better alternative mesh than polypropylene?
- A I don't agree with your use of the word "alternative."
- Q Well, I'm trying to understand your opinions, Doctor. So what I'm asking you is, is

Page 252 through the 510(k) process, which in my opinion is

2 inadequate to demonstrate the safety of these3 meshes.

4 MS. JONES: Move to strike as 5 nonresponsive.

6 BY MS. JONES:

- Q My question, Doctor, was this: Is it your testimony and your opinion that no mesh should be on the market for the transvaginal treatment of prolapse?
- A My opinion is that if a mesh belongs on the market for the transvaginal treatment of prolapse, the safety needs to be established first.

14 MS. JONES: Move to strike as 15 nonresponsive.

16 BY MS. JONES:

- Q As we sit here today, Doctor, is it your opinion that no mesh used for transvaginal treatment of prolapse should be on the market?
- A I believe I answered that question. To my understanding, all of the products currently on the market have gone through 510(k) process, which in my opinion is insufficient to establish their safety. If they're not safe, they don't belong on the market.

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there a better mesh of which you are aware than the polypropylene mesh?

A A yes or no answer would not -- would be misleading. You're suggesting that there's a comparison to be made. I can use the words of one of Ethicon's own employees: The best of a bad lot, talking about polypropylene.

MS. JONES: Move to strike as nonresponsive.

BY MS. JONES:

- Q My question, Doctor, doesn't relate to polypropylene. My question relates to whether or not you have an opinion that there is a mesh that has better characteristics for implantation in the body than polypropylene.
- A $\,$ I have answered that I don't believe a mesh exists that's appropriate for transvaginal implantation for Prolift® -- prolapse. Excuse me.
- Q So it would be your opinion that no mesh should be on the market for the transvaginal treatment of prolapse?

A I believe that the mesh -- let me start again. The greater part of my knowledge revolves around Gynemesh® PS mesh used in Prolift®. To my understanding, every product on the market went

Q So your opinion is that no mesh currently used for the transvaginal treatment of prolapse should be on the market?

A I believe I answered that question.

Q I'm just asking you, Doctor, am I correct that that is your opinion?

A I don't believe that -- I believe I've answered that question and I don't believe that question can be answered with a simple yes or no.

- Q Well, tell me then, Doctor, identify for me as you sit here today the mesh that you believe should be on the market for the transvaginal treatment of prolapse.
- A I already told you I don't believe that mesh exists at this point in time.
- Q Do you know how many doctors in this country have used polypropylene mesh for the transvaginal treatment of prolapse?

A No.

- Q You do know that a significant number of surgeons in this country have used transvaginal mesh for the treatment of prolapse; correct?
 - A I know that a significant number of surgeons have used mesh and have abandoned it because they believe it's too unsafe to be used in

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Page 254 Page 256 their patients. complications noted in the studies, whether it's 1 1 2 Q You know that not every woman who has had 2 case studies or randomized trials, does it not? A It may. It may not be complete or 3 transvaginal mesh used to correct prolapse has 3 4 experienced complications, don't you? 4 accurate. For example, in the TVM studies that were 5 A Not yet. These women are at lifelong risk 5 published, the five-year study that was published in the medical literature is inaccurate and does not for complications from the permanent implantation of 6 6 7 Prolift® mesh. 7 accurately provide the extent of complications 8 8 experienced by women who had the TVM procedure. O Based upon the studies and the literature Q As I recall, Doctor, you have never 9 that are out there, 75 to 80 percent of the women 9 who have transvaginal mesh used to correct prolapse examined a woman that's had Prolift®; is that 10 10 11 have had no major complications; correct? 11 correct? A Not yet. There is no safe time -- one of 12 12 A That is correct. your experts in the medical literature -- there is 13 13 Q Have you ever spoken with a woman that's no safe time after mesh implantation for eliminating had Prolift®? 14 14 the risk of complications. A It's not on her forehead. 15 15 MS. JONES: Move to strike as 16 16 Q I'm sorry? A It's not on her forehead. Not to my 17 nonresponsive. 17 18 BY MS. JONES: 18 knowledge. Have you ever done --Q As we sit here today, today, Doctor, 75 to 19 19 20 80 percent of the women who have had transvaginal 20 MR. SLATER: Do you want to take a mesh correction of Prolift® have experienced no 21 21 break? significant, major complications; correct? 22 22 THE WITNESS: Is this a good time for MR. SLATER: Objection. 23 23 a break? 24 THE WITNESS: Where do you get the --24 MR. SLATER: If you need a break, 25 MR. SLATER: You can go ahead. 25 it's a good time. Page 257 Page 255 THE WITNESS: Where do you get the 75 1 BY MS. JONES: 1 2 to 80 percent? 2 O Let me ask this question first. Have you 3 BY MS. JONES: 3 ever done any separate analysis, Doctor, of any literature regarding Prolift® complications? 4 Q Well, let me just ask you first, do you 4 5 agree with that? That's my question. 5 MR. SLATER: What do you mean by a 6 A I would like to know the basis for your 6 "separate analysis"? Beyond what she's done in this 7 question. I would like to know the basis for which 7 case? 8 8 you claim that 75 to 80 percent of women after THE WITNESS: What do you mean by 9 Prolift® implantation have not had significant, 9 "separate analysis"? major complications. 10 BY MS. JONES: 10 Q You know, Doctor, I get to ask the Q Have you ever sat down, Doctor, and done a 11 11 meta-analysis of studies involving Prolift®? 12 auestions here. 12 13 A And I get to have the questions clarified. 13 A No. Q Well, my question to you is do you agree MS. JONES: Let's take a break. 14 14 15 with that figure or not? 15 (Short recess.) A I am not going to agree with that BY MS. JONES: 16 16 statement on the basis of a lack of clarification. Q Doctor, in your reports that outline your 17 17 18 Q Have you looked at the medical literature 18 opinions in this case, have you set forth your criticisms of the medical literature and the with respect to the use of transvaginal mesh? 19 19 20 A Short term. 20 individual studies? Q My question, Doctor, is have you looked at 21 21 Α Yes. the medical literature with respect to the use of 22 22 Q To the best of your knowledge as you sit transvaginal mesh? here today, have you identified all of those 23 23 24 A Yes. 24 criticisms? 25 25 And that medical literature reports on A Yes. Q

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O If we turn to the instructions for use for Prolift®, you have opinions about the adequacy of the warnings that were included within them; am I

correct?

A Yes.

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Q Can you tell me, Doctor, or just summarize for me, if you would, your opinions of what should have been in the IFU in terms of complications that were not in there and when they should have been included?

MR. SLATER: Do you mind if she has her report available or the IFU available? Because she has nothing in front of her right now.

MS. JONES: I understand. And I will stipulate to you that whatever is in the report is in the report. I'm not trying to trick you. I'm just trying to move quickly through this.

MR. SLATER: Because it's kind of hard to remember everything sitting here.

THE WITNESS: I would prefer to have my report.

MS. JONES: Then you're more than welcome.

MR. SLATER: Unless counsel might want you to just throw out a couple and she's just

Page 258 1 when they should have been included?")

THE WITNESS: Well, I can answer the

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last part of the question first. Clearly they

4 should have been included from the moment Prolift® 5 was on the market.

BY MS. JONES:

Q While you're looking for that, Doctor, is it your testimony that you believe that every potential complication associated with the use of Prolift® was known at the time that it was first marketed?

A I understand that was the testimony of Ethicon employees; yes.

O I was asking really for your opinion at 14 15 the time.

A No. My opinion at the time was that all of the risks were not known and that evolved over time. In fact --

How do you understand that those risks --0

-- the treating physicians of the plaintiffs testified that they learned over time several of the contraindications and additional risks that Ethicon failed to inform them of.

Q What is your understanding of how that 25 evolved over time?

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going to ask you questions about the few that you come up with now as long as we understand --

MS. JONES: If you want to have your report, you can have it. I was, frankly, just trying to move along guickly in the hopes we could finish today. I'm not trying to put anybody at a disadvantage.

MR. SLATER: I'm fine with doing this. I just don't want it to be construed later that her testimony was some complete list. That's all. As long as we have that understanding, it's fine. It's up to you.

MS. JONES: I'm willing to say that whatever's in the report is in the report. I'm not trying to trick you in any way, shape, or form. But I'm also willing to let you have the report and go through it.

THE WITNESS: Could you repeat the question, please?

(The court reporter read the record as follows:

"QUESTION: Can you tell me, Doctor, or just summarize for me, if you would, your opinions of what should have been in the IFU in terms of complications that were not in there and 1 A My understanding is that patients with

2 preexisting chronic pain conditions are contraindicated to undergo the Prolift® procedure 3

because they are at such higher risk of developing 4

5 either an exacerbation of their preexisting

condition or the development of a new pain condition 7 and that was not warned of at the time of Prolift®

launch.

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O Let me ask you this, Doctor: In terms of women with a chronic pain condition, those women would be at increased risk of pelvic pain regardless of the type of surgery that was performed, would they not?

A That is not my clinical experience.

Q In the course of your clinical experience, did you perform prolapse surgery on patients with a chronic pain syndrome?

A Yes.

19 Q Tell me what types of chronic pain 20 syndrome you would perform surgery on.

A Fibromyalgia, arthritis, migraine 21

headaches. That's all I can think of at the moment. 22

23 Q Do you have any idea as you sit here today how many women you performed prolapse surgery on who 24 25 had fibromyalgia?

Page 262 Page 264 pain conditions? 1 I do not know. 1 2 Q How about how many women had migraine 2 Q I am, if that's what you would --3 3 A Okay. To the best of my recollection at headaches? 4 4 the moment, I already mentioned fibromyalgia, A I do not know. 5 arthritis -- I can't remember the third thing I 5 Q Did you take any special precautions for women who had chronic pain syndrome? 6 6 said. 7 A I counseled them that in the immediate 7 Q You said migraines. 8 8 Migraines. Thank you. Interstitial postoperative period they may experience more pain cystitis, endometriosis. Many chronic pain 9 and we will do everything we can to manage that 9 effectively for them. Outside of the immediate four syndromes don't have a diagnosis. They are 10 10 to six weeks after surgery, that should have 11 11 described as a chronic pain syndrome. I'm trying to give you a list of the conditions that actually have 12 resolved to baseline. 12 a diagnosis. 13 Q Did you counsel all women whom you knew 13 had had chronic pain conditions about that? 14 14 Well, can you give me some -- other than That would have been my practice. what you've already given, are there other examples 15 15 of complaints that women had experienced that would Is that something that you think would be 16 16 a standard practice for surgeons performing prolapse prompt you to have the conversation with them about 17 17 18 surgery? 18 chronic pain and any increased risk? A Pelvic muscle spasm. I can't think of any 19 A I don't want to speak for all surgeons 19 20 performing prolapse surgery. 20 other conditions at this time. Q Is that something that you trained your 21 Q If you became aware as a physician that a 21 patient had complained of significant pain following 22 residents to do? 22 earlier surgical procedures, would you have 23 23 A Yes. 24 Q Is that something that you trained your 24 counseled them on that? 25 MR. SLATER: Objection; ambiguous. 25 fellows to do? Page 263 Page 265 Α Yes. 1 You can answer. 1 2 O Is that something that you did beginning 2 THE WITNESS: Significant pain that in the course of your residency? 3 3 became chronic? A I don't remember that specifically. 4 4 BY MS. JONES: 5 Q When did you begin to counsel patients 5 Q That's what I'm trying to ask you. I'm about chronic pain syndromes? trying to understand under what circumstances you 6 6 A That would have been in my residency when 7 7 would counsel patients on chronic pain and any 8 8 they were surgical candidates. increased risk. Q So from the time you were in your 9 9 MR. SLATER: Objection; ambiguous. residency, you would have counseled patients on 10 10 You can answer. those chronic pain situations? THE WITNESS: I don't know that I can 11 11 12 12 add to the list I've already given you. Correct. 13 Q And that was something that you were 13 BY MS. JONES: trained to do in your residency? Q But you would counsel patients about that 14 14 15 A Correct. 15 regardless of the type of prolapse surgery that you Q And what do you consider to be chronic were going to perform? 16 16 pain conditions or syndromes? MR. SLATER: Objection. 17 17 18 A I don't understand your question. Are you 18 You can answer. THE WITNESS: Yes, yes. asking again for a list of chronic pain conditions? 19 19 20 20 Q I am. BY MS. JONES: All chronic pain conditions? Q I mean, it didn't make any difference 21 21 Α Q What I'm asking for is a list, Doctor, of whether it was a vaginal sacrospinal ligament 22 22 the conditions that would prompt you to counsel fixation or an abdominal sacrocolpopexy? 23 23 24 patients about that. 24 A Correct. 25 A So you're asking for a list of all chronic 25 Q Other than the chronic pain syndrome that

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you just mentioned, are there other complications that you believe should have been included within the IFU at the time of launch?

- A Infection potentiation was included as a risk and that is an inadequate statement to --
 - Q I'm sorry. What --

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- Α Oh, Page 405. And that is an inadequate description of the nature and extent and severity of the kinds of infectious complications that can occur after the Prolift® procedure and permanent Prolift® mesh implantation.
- Q Can you identify for me, Doctor, any studies that show a statistical significant increased risk of infection associated with Prolift®?
- A There are two types of infections. The first type of infection is an acute infection, an abscess, as an example. And to my knowledge, that type of infection has not been increased after Prolift® procedures.

The second type of infection is a chronic low-grade infection, and that is something that occurs more commonly after Prolift® surgery than after native tissue repair.

Q And can you tell me what study you're

A I don't think I would label it a 1 2 hypothesis.

Q Then can you identify for me a study that shows a statistically significant increased risk of a low-grade infection?

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A Mesh erosion.

I'm asking you for a study. Can you just identify for me what it is that you're relying upon when you make those comments?

MR. SLATER: With all due respect, I'm not going to go through what she said -- and you're tilting your head at me -- but, you know, she's given you a very, very specific answer and given you chapter and verse on a whole extent of literature.

MS. JONES: Counsel, I've asked four times --

MR. SLATER: And you've gotten a direct answer.

MS. JONES: I have asked four times for the identification of a study and we don't have a study that's been identified yet. If there's not one, there's not one.

24 BY MS. JONES:

Q I'm just asking what it is specifically

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relying upon when you say that?

A Because Ethicon failed to study the etiology of mesh erosion, the etiology is not completely understood. Surgeons believe that a chronic low-grade infection is responsible for mesh erosion and recurrent mesh erosion. And in that way that is an example of a chronic low-grade infection that can only occur after mesh implantation and specifically Prolift®.

Q Doctor, my question was really can you identify specifically for me what you're relying upon when you make those statements?

A All of the articles that demonstrate at least a 10 percent -- not at least -- an average of 10 percent and many studies showing much higher rates of mesh erosion.

Q Erosion, not infection, erosion?

Again, because the etiology is not understood because Ethicon failed to study this, mesh -- surgeons are still trying to figure out what causes mesh erosion. And it's plausible from a biological standpoint that these are low-grade subclinical infections and are causing mesh erosion and recurrent mesh erosion.

Q And that is a hypothesis at this point?

that you rely upon. What is it that you rely upon for those statements?

A The Altman study didn't even report the number of patients who experienced mesh erosion. It reported the number of patients who required surgery for mesh erosion. Every single study of Prolift® in the literature identifies that specific rate of mesh erosion in that study. That's the studies -- those are the studies I am relying on.

Q So you're relying on erosion as being identical to infection?

A To the best of my understanding in 2012, because Ethicon failed to study this and understand the etiology of mesh erosion before they put the Prolift® or even the Gynemesh® PS mesh on the market, etiology of mesh erosion is not completely understood. To my understanding, the most logical explanation is a subclinical low-grade infection because the mesh is contaminated on placement and that contamination cannot be cleared. It shows itself as mesh erosion and recurrent mesh erosion. MS. JONES: Move to strike as nonresponsive.

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24 BY MS. JONES:

Q Doctor, tell me, if you would, what you

Page 270 Page 272 rely upon in support of your opinion that a 1 1 erosion? 2 subclinical infection causes mesh erosion. 2 A In addition --MR. SLATER: In addition to what she 3 3 MR. SLATER: Same objection. 4 4 just told you, counsel? You can answer again. 5 5 THE WITNESS: In addition to all the MS. JONES: I'm just asking her to 6 6 evidence in the medical literature, I rely on the tell me. 7 MR. SLATER: Hang on. It's asked and 7 experience and opinion of surgeons who are 8 answered. So I'm asking you do you want her to 8 experienced in caring for women who have mesh repeat what she said or in addition to what she 9 9 erosion and recurrent mesh erosion and who have studied this over their years of clinical practice 10 said? 10 11 MS. JONES: I want her to tell me 11 in order to somehow find a better way to treat these 12 what she relies upon specifically --12 women, because we don't --MR. SLATER: She just told you. 13 13 BY MS. JONES: MS. JONES: -- for the opinion that a 14 14 O Can you name those surgeons for me? subclinical infection causes erosion. 15 15 A Dr. Shlomo Raz. Q Anybody else? 16 MR. SLATER: And you were asking in 16 the literature. Now it goes beyond the literature? A I don't remember his name. He is the 17 17 18 She can bring out anything else? 18 infectious disease expert from the University of MS. JONES: I've never gotten 19 19 Connecticut. 20 anything out of the literature. 20 Q Okay. The infectious disease expert in MR. SLATER: Well, you have. She 21 this litigation? 21 22 listed every single Prolift® study with erosion 22 Α Yes. 23 23 Q Anybody else? rates. 24 MS. JONES: Counsel, come on. It's 24 That's all I can think of off the top of 25 25 my head. inappropriate. Page 271 Page 273 MR. SLATER: It's not inappropriate. 1 1 Do you believe, Doctor, and is it your 2 2 opinion that the erosions associated with She said it three times. 3 MS. JONES: It is inappropriate. And 3 transvaginal mesh are different from the erosions I don't want to go to the judge, but even the judge 4 4 with other mesh? 5 is going to recognize these are speaking objections. 5 MR. SLATER: Objection to the form. 6 We've got an expert witness here who can answer the 6 You can answer. questions. This is inappropriate. 7 7 Highly ambiguous. 8 8 MR. SLATER: Well, it's You can answer. inappropriate, too, for counsel to pretend that an 9 THE WITNESS: Yes. 10 answer hasn't been given and to continue to ask the 10 BY MS. JONES: same question because you don't like the answer. 11 11 Q How? MS. JONES: No. I haven't gotten the 12 12 The mesh is implanted through what is answer. And we can look at it and we can ask Judge termed surgically a clean contaminated environment. 13 13 It's laden with bacteria from the moment it's in the 14 Highee to look at it. 14 15 MR. SLATER: You have the right to do 15 woman's body. that. I feel very confident that what I'm doing is Q That's with the transvaginal mesh? 16 16 appropriate right now. 17 Correct. 17 Α 18 MS. JONES: Well, I don't think it's 18 What causes erosion in the mesh used in appropriate, what Judge Higbee thinks is 19 19 abdominal sacrocolpopexy? 20 appropriate. So I'm going to ask the question one 20 A The characteristics of the mesh incite an inflammatory reaction and foreign body reaction that 21 more time. 21 22 BY MS. JONES: 22 disturbs the surrounding tissue and results in the 23 Q I'd like, Doctor, for an answer to the formation of an erosion. 23 question. Specifically what is it upon which you Q And that's different from what happens 24 24 25 rely that says a subclinical infection causes 25 with a transvaginal mesh?

Page 274 Page 276 things that you've noted and say you have completely A Are you asking me to differentiate 1 1 2 abdominal sacrocolpopexy? 2 set out your opinions here in your report? 3 3 Q I'm asking you how the erosions that occur A My opinions are completely set out in my 4 with meshes not used in transvaginal surgery are 4 report. 5 5 caused and how those differ from what's used in MR. SLATER: Obviously, counsel, 6 transvaginal surgery. 6 there are supplemental reports, too. 7 MR. SLATER: Objection to the form. 7 BY MS. JONES: 8 8 You can answer. O Doctor, have you ever talked with or THE WITNESS: First of all, in 9 9 visited with a surgeon who has used Prolift® to 10 abdominal sacrocolpopexy the mesh is placed on the 10 treat women? outside of the vagina from an internal basis. In You mean specific to the Prolift®? 11 11 Α transvaginal mesh implantation, the vagina is 12 Q Yes, ma'am. 12 incised, dissected, creating whatever level of 13 13 Α tissue damage occurs with incisions and dissection. 14 14 0 Have you ever spoken with a doctor who has And, as I said, the mesh is contaminated in gone through the Prolift® professional education 15 15 placement because of the natural vaginal program about that program? 16 16 microenvironment that cannot be sterilized at the 17 17 Α No. 18 time of surgery. The surgical field cannot be 18 Have you ever spoken with a doctor who has gone through either a proctorship or a preceptorship separated, draped in such a way as to isolate a 19 19 20 specific area that you're operating on in order to 20 with respect to Prolift®? prevent the introduction of bacteria with mesh 21 Α No. 21 implantation. That's one reason. 22 22 Have you ever attended any professional meetings where studies with respect to Prolift® were 23 BY MS. JONES: 23 24 Q I'm sorry, Doctor. We're just not 24 specifically discussed? A Yes. 25 communicating. If you have mesh that's used in 25 Page 275 Page 277 abdominal sacrocolpopexy, there have been reports of 1 Q What were those? 1 2 erosion; correct? 2 I don't remember specifically. It would be in the years between 2005 and 2007, the end of 3 A Vaginal erosions, correct. 3 2007, when I was still attending professional And my question to you is whether or not 4 4 5 the cause of those erosions is different from the 5 meetings. 6 cause of the erosions you see with transvaginal 6 Do you remember who presented? Q 7 7 mesh. Α 8 8 A As I've already said, the etiology of 0 Do you remember what study was presented? 9 erosions is not fully understood. Mesh -- bacterial 9 Α No. 10 contamination of the mesh is logical in 10 Q Do you remember anything about any understanding why mesh erosion occurs and why mesh discussion at the time? 11 11 erosion occurs so much more frequently in 12 12 Discussion, very controversial. Doctors transvaginal Prolift® mesh implantation than in were very gravely concerned that the widespread use 13 13 abdominal mesh implantation. of mesh was happening without evidence of safety 14 14 15 Q And so is the answer that as you sit here 15 and, in fact, with strong evidence of grave harm to today, you don't know whether or not there's a patients without demonstrated benefit. 16 16 different etiology for mesh erosion associated with O Can you identify for me, Doctor, any 17 17 18 abdominal sacrocolpopexy versus the transvaginal 18 doctors who expressed that view? A Dr. Ingrid Nygaard; Dr. Peggy Norton; 19 inserted mesh? 19 20 A That is correct. The etiology of mesh 20 Dr. Linda Brubaker; Dr. Mary Pat FitzGerald; 21 erosion is not completely understood. Dr. Matt Barber; Dr. Scott Smilen, S-M-I-L-E-N; 21 Dr. Robert Porges, P-O-R-G-E-S; Dr. Bob Shull, 22 O We started this discussion when we were 22 23 talking about your criticisms of the IFU. And I 23 S-H-U-L-L. Do you want me to keep going?

Q All of these doctors expressed a view at

this meeting that you attended?

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guess my question, Doctor, is if we go through this,

are you going to take me through each one of these

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	Connachtial Subject to Supula		, , , , , , , , , , , , , , , , , , ,
	Page 278		Page 280
1	A I'm reflecting on a number of meetings.	1	has been restricted to abdominal use.
2	Q How many meetings did you attend where	2	MS. JONES: Move to strike as
3	Prolift® was discussed?	3	nonresponsive.
4	A I can estimate four to six.	4	BY MS. JONES:
5	Q And can you tell me what meetings they	5	Q Doctor, my question was: Do you know how
6	were?	6	many fellowship programs continue to train fellows
7	A I can tell you what meetings they were	7	on the use of transvaginal mesh to treat prolapse?
8	likely to be. The American Urogynecologic Society	8	A No, I don't.
9	and the Society of Gynecologic Surgeons.	9	Excuse me. I'd like to take two minutes
10	Q And you would have attended four to six of	10	to go to the restroom.
11	those between 2005 and 2007?	11	MS. JONES: Please.
12	A They're held annually so that would be	12	(Short recess.)
13	six, yes. They're separate meetings. Three years,	13	BY MS. JONES:
14	two meetings a year, six meetings.	14	Q Doctor, I'm going to talk about Ms. Gross
15	Q I asked you to identify for me the people	15	for a second. So until and unless I tell you
16	that expressed concerns. There were also people	16	something else, that's who we're going to be talking
17	expressing the other side of that, were there not?	17	about. Okay?
18	A Yes. Those doctors were largely paid by	18	A Okay.
19	Ethicon.	19	Q As I understand the opinions that have
20		20	been set forth in your report, you believe that she
	Q There were doctors who were not paid by Ethicon that were involved in and used mesh, did	21	experienced left pudendal neuralgia from Prolift®;
21 22		22	am I correct?
	they not? A Yes.	23	A Correct.
23			
24 25	Q Do you remember any of the presentations	24 25	Q Partial urinary retention? A Correct.
25	where doctors suggested that the use of transvaginal	25	A Correct.
	Page 270		Dama 201
1	Page 279 mesh was appropriately used for prolapse?	1	Page 281 Q Mesh erosion and exposure?
1	A No, I do not remember specific	1 2	Q Mesh erosion and exposure? A Correct.
2	presentations.	3	
4	Q Do you remember the names of any doctors	4	Q Fear, anxiety, and depression? A Correct.
5	who presented on that?	5	Q And that she is fully disabled?
6	A Not specifically.	6	A Correct.
7	Q Do you remember whether or not you ever	7	Q Now, did I correctly summarize the
8	saw any presentation involving any of the members of	8	case-specific opinions that you have with respect to
9	the TVM group?	9	Ms. Gross and her injuries?
10	A I don't remember specifically.	10	A Yes.
11	Q Do you know how many academic institutions	11	Q I know that you testified yesterday that
12	were training surgeons on the use of transvaginal	12	you were initially contacted in this litigation in
13	mesh?	13	the fall of 2009. When were you first asked to
14	A No.	14	review the medical records of Ms. Gross?
15	Q Do you know how many fellowship programs	15	A I don't know specifically.
16	trained fellows on the use of transvaginal mesh?	16	Q Can you give me an approximation of when
17	A No.	17	you first began to review Ms. Gross' medical
18		18	records?
19	Q Do you know how many fellowship programs continue to train fellows or surgeons on the use of	19	A No.
20	transvaginal mesh for treatment of prolapse?	20	Q Can you tell me how long you spent
21	A Well, they can't train on Prolift® because	21	reviewing Ms. Gross' medical records in preparation
22	it's been pulled off the market and	22	of that report?
23	MS. JONES: Move to strike as	23	A No, I can't estimate that.
23 24	nonresponsive.	23 24	MS. JONES: Counsel, I think you told
25	THE WITNESS: Gynemesh® PS mesh	25	me yesterday that you would get a copy of the
23	THE WITHESS. Synchication 13 mesti	23	The yesterday that you would get a copy of the

Page 282 Page 284 1 A If I understand your question correctly, 1 financial disclosure. 2 MR. SLATER: Oh, yeah. It's sitting 2 you're asking me to identify something that I don't 3 know I've seen. So I don't know how to answer that. 3 around the corner. Want me to look for it now? 4 4 Q I'm asking the guestion because, frankly, MS. JONES: Well, no, but let's get 5 5 Doctor, what I looked at earlier in terms of the it at the break. materials reviewed didn't necessarily have all the 6 MR. SLATER: Absolutely. 6 7 MS. JONES: Because I would like to 7 Bates numbers and all there so I can't tell exactly 8 8 what you've reviewed from each doctor's files. But see it before and mark that. I do know that you can sometimes review the files 9 MR. SLATER: I have the packet with 9 and it's apparent that you don't have the complete 10 all the experts so I'll give you the whole thing, 10 because apparently no one showed it to you. 11 file from a given doctor. And that's what I'm 11 MS. JONES: I'm not suggesting --12 12 asking you. MR. SLATER: They're so busy passing A I -- it was not obvious to me that chunks 13 13 notes to you they're not giving you our disclosures. 14 14 were missing. I can't say for certainty otherwise. Q That's all I'm asking. I'm just asking 15 BY MS. JONES: 15 whether or not, to the best of your knowledge, you 16 Q Is there any way, Doctor, that you can 16 separate out for us the time that you spent received the complete file from each of the doctors 17 17 18 reviewing and preparing your opinions with respect 18 whose records you reviewed. A Well, again, complete. For example, to Ms. Gross? 19 19 20 A No. 20 Dr. Likness cared for Mrs. Gross, I don't know, what beginning -- beginning at what age, but he was her Q Would the answer be the same with respect 21 21 lifetime family physician. So have I reviewed every 22 to Ms. Wicker? 22 page of her medical records related to Dr. Likness? 23 23 A Yes. 24 Q And I think it's implicit in what I just 24 Probably not. 25 asked you, but it is also correct then that you did 25 Q Were you furnished with any summary of the Page 283 Page 285 not separately invoice Mr. Slater for the 1 medical records? 1 2 2 preparation of your opinions with respect to Α Yes. 3 Ms. Gross? 3 Were you furnished with a summary of the 4 A Correct. 4 medical records for both Ms. Wicker and Ms. Gross? 5 Q Or Ms. Wicker? 5 Α 6 6 Do you know who prepared that summary? A Correct. Q 7 7 O To the best of your knowledge, have you I don't remember. reviewed the complete medical records of Ms. Gross? 8 8 MS. JONES: I know we're going to 9 A Complete as in her whole life? 9 have an argument about this, but I'm going to 10 Q Well, have you reviewed the complete 10 request those summaries. medical records of every doctor whose records you MR. SLATER: You can send me a 11 11 12 have reviewed? 12 letter. I mean, my position is that they were provided only to give an idea of what was being 13 A Yes, all material provided to me I have 13 provided, that Dr. Weber relied on the records, not 14 reviewed. 14 15 Q But that's not really my question. My 15 on the summary, so it's work product. question is: Did you receive excerpts from my MS. JONES: Well, I know that's your 16 16 position. We'll take it up later. But I'm going to doctors' files? 17 17 18 A No. Well --18 ask for those. And I would ask you --Q Here's the question: Sometimes doctors MR. SLATER: Are you going to send me 19 19 only receive copies of the operative reports, for 20 all your summaries? Are you going to send me all 20 example, and not the notes. And that's all I'm the summaries that you did for your experts? 21 21 asking is whether or not you reviewed the complete MS. JONES: I don't send summaries to 22 22 records of the doctors that you have identified in 23 23 my experts. 24 the supplemental materials reviewed or whether you 24 MR. SLATER: Someone does. only received certain portions of those files. 25 MS. JONES: Not that I know of. 25

	Page 286		Page 288
1	BY MS. JONES:	1	Q Yes.
2	Q Do you know whether or not you received	2	A Yes.
3	those summaries were they in electronic form or	3	Q Did you review summaries of the
4	hard copy?	4	depositions?
5	A Electronic.	5	A In some cases, yes.
6	Q I'm going to ask you, just as I did	6	Q Were you furnished summaries of all of the
7	yesterday, if you would maintain those permanently	7	depositions?
8	up until the time of trial and so forth so that when	8	A No.
9	the Court decides what's appropriate for us to get	9	Q Can you tell me what summaries you
10	or not we will have access to them. Okay?	10	reviewed of the depositions?
11	A Yes.	11	A Dr. Benson. That's the only one I can
12	Q Do you know any of the treating physicians	12	remember.
13	for Ms. Gross?	13	Q I asked you, Doctor, when you had reviewed
14	A No.	14	the information that relates to Ms. Gross. You said
15	Q Are you familiar with Dr. Antolak?	15	you couldn't remember. Did you actually look at it
16	A Antolak?	16	during this year, 2012?
17	Q Uh-huh.	17	A Yes.
18	A I don't know how to say his name either.	18	Q Had you looked at any portion of those
19	I'm familiar with him now, of course.	19	records before?
	'	20	A Yes.
20	- , , ,	21	
21 22	in what sense are you familiar with him now?	22	Q Do you remember whether or not you looked at them before the fall of 2011?
	A In the course of being a treating	23	
23	physician for Mrs. Gross.		A I don't remember.
24	Q Have you reviewed his deposition?	24	Q Did you receive summaries of any of the
25	A Honestly, I need my list of materials	25	depositions of the Ethicon witnesses?
	Page 287		Page 289
1	reviewed to know for sure.	1	A Yes.
2	Q I will represent to you I did not see it	2	Q Tell me which witnesses you received
3	listed on your materials reviewed so I'm	3	summaries on.
4	MR. SLATER: Wait. You're looking at	4	A To the best of my recollection, Dr. Piet
5	the wrong list then.	5	Hinoul. That's all I can remember.
6	MS. JONES: Well, I may be.	6	Q Did you receive complete deposition
7	MR. SLATER: There's been updated	7	transcripts on the Ethicon witnesses?
8	lists. I'm just telling you. He's definitely	8	A Yes.
9	listed. I'll find out during lunch.	9	Q Did you receive all of the exhibits to
10	MS. JONES: I mean, let's do this	10	those depositions?
	•	11	A No.
11	during lunch: Can we get what you believe is the		
11 12	during lunch: Can we get what you believe is the complete list		
12	complete list	12	Q Have you requested any other Ethicon
12 13	complete list MR. SLATER: Absolutely.	12 13	Q Have you requested any other Ethicon documents for review that you've not yet seen?
12 13 14	complete list MR. SLATER: Absolutely. MS. JONES: of everything at	12 13 14	Q Have you requested any other Ethicon documents for review that you've not yet seen? A No.
12 13 14 15	complete list MR. SLATER: Absolutely. MS. JONES: of everything at lunch?	12 13 14 15	Q Have you requested any other Ethicon documents for review that you've not yet seen? A No. Q Before you reviewed the deposition of
12 13 14 15 16	complete list MR. SLATER: Absolutely. MS. JONES: of everything at lunch? MR. SLATER: Yes.	12 13 14 15 16	Q Have you requested any other Ethicon documents for review that you've not yet seen? A No. Q Before you reviewed the deposition of Dr. Antolak, were you familiar with his reputation
12 13 14 15 16 17	complete list MR. SLATER: Absolutely. MS. JONES: of everything at lunch? MR. SLATER: Yes. MS. JONES: Just check, because I	12 13 14 15 16 17	Q Have you requested any other Ethicon documents for review that you've not yet seen? A No. Q Before you reviewed the deposition of Dr. Antolak, were you familiar with his reputation as a specialist on pudendal neuralgia?
12 13 14 15 16 17 18	complete list MR. SLATER: Absolutely. MS. JONES: of everything at lunch? MR. SLATER: Yes. MS. JONES: Just check, because I will represent to you that what I was looking at did	12 13 14 15 16 17 18	Q Have you requested any other Ethicon documents for review that you've not yet seen? A No. Q Before you reviewed the deposition of Dr. Antolak, were you familiar with his reputation as a specialist on pudendal neuralgia? A No. Well, let me just say in reviewing
12 13 14 15 16 17 18 19	complete list MR. SLATER: Absolutely. MS. JONES: of everything at lunch? MR. SLATER: Yes. MS. JONES: Just check, because I will represent to you that what I was looking at did not have that deposition transcript listed.	12 13 14 15 16 17 18 19	Q Have you requested any other Ethicon documents for review that you've not yet seen? A No. Q Before you reviewed the deposition of Dr. Antolak, were you familiar with his reputation as a specialist on pudendal neuralgia? A No. Well, let me just say in reviewing the records of Mrs. Gross, she had seen Dr. Antolak.
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12 13 14 15 16 17 18 19 20 21 22	complete list MR. SLATER: Absolutely. MS. JONES: of everything at lunch? MR. SLATER: Yes. MS. JONES: Just check, because I will represent to you that what I was looking at did not have that deposition transcript listed. BY MS. JONES: Q Did you receive the entire deposition transcripts for the doctors and witnesses that you	12 13 14 15 16 17 18 19 20 21 22	Q Have you requested any other Ethicon documents for review that you've not yet seen? A No. Q Before you reviewed the deposition of Dr. Antolak, were you familiar with his reputation as a specialist on pudendal neuralgia? A No. Well, let me just say in reviewing the records of Mrs. Gross, she had seen Dr. Antolak. So at that point I became aware of his specialty in pudendal neuralgia. So that would be at some time before his deposition.

	Page 290		Page 292
1	the medical literature.	1	A I cannot say for sure.
2	Q And did you do any searches on any of	2	Q Are the photomicrographs specifically
3	Ms. Gross' other doctors?	3	identified on the list of materials reviewed
4	A Yes; Dr. Hibner, again from the medical	4	according to which institution they would have come
5	literature.	5	from?
6	Q And did you pull and review any of the	6	A No.
7	medical articles written by either Dr. Hibner or	7	Q Are they identified in any way?
8	Dr. Antolak?	8	A I believe they're identified by her name,
9	A Yes.	9	Linda Gross, and by a number.
10	Q And are the articles that you pulled and	10	Q And what do you think that number refers
11	reviewed identified on the list of materials	11	to?
12	reviewed?	12	A I don't know.
13	A Yes, if there were articles.	13	Q You don't know whether they're exhibits to
14	Q Let me ask you this: Do you recall	14	the deposition or whether they're something from the
15	reading articles authored by either of those two	15	medical records?
16	doctors?	16	A They may have been used as exhibits. They
17	A I can't be sure. If I read them, they're	17	are not labeled as exhibits.
18	on the list.	18	MS. JONES: Counsel, I'm going to ask
19	Q Let me ask you, have you reviewed any	19	specifically that those photomicrographs be
20	materials from the Social Security Administration on	20	produced.
21	Ms. Gross?	21	MR. SLATER: You have them already.
22	A No.	22	MS. JONES: I just want to know which
23	Q You identified three experts' reports that	23	ones they are so that we
24	you had reviewed before preparing your opinions, and	24	MR. SLATER: You have them all. She
25	those were those of Dr. Serrato, Dr. Welch, and	25	was given everything I produced to you. When
	Page 291		Page 293
1	Page 291 Dr. Provder; is that correct?	1	Page 293 Dr. Welch's report was produced, we gave you all of
1 2		1 2	-
	Dr. Provder; is that correct?	_	Dr. Welch's report was produced, we gave you all of
2	Dr. Provder; is that correct? A Mr. Provder, yes.	2	Dr. Welch's report was produced, we gave you all of the photomicrographs of every single slide he looked
2	Dr. Provder; is that correct? A Mr. Provder, yes. Q And did you rely upon the report of	2	Dr. Welch's report was produced, we gave you all of the photomicrographs of every single slide he looked at and those were provided to Dr. Weber.
2 3 4	Dr. Provder; is that correct? A Mr. Provder, yes. Q And did you rely upon the report of Dr. Serrato in formulating your opinions?	2 3 4	Dr. Welch's report was produced, we gave you all of the photomicrographs of every single slide he looked at and those were provided to Dr. Weber. MS. JONES: That's all I'm trying to
2 3 4 5	Dr. Provder; is that correct? A Mr. Provder, yes. Q And did you rely upon the report of Dr. Serrato in formulating your opinions? A Yes.	2 3 4 5 6 7	Dr. Welch's report was produced, we gave you all of the photomicrographs of every single slide he looked at and those were provided to Dr. Weber. MS. JONES: That's all I'm trying to figure out is what photomicrographs Dr. Weber has
2 3 4 5 6 7 8	Dr. Provder; is that correct? A Mr. Provder, yes. Q And did you rely upon the report of Dr. Serrato in formulating your opinions? A Yes. Q Did you review the ultrasounds that Dr.	2 3 4 5 6	Dr. Welch's report was produced, we gave you all of the photomicrographs of every single slide he looked at and those were provided to Dr. Weber. MS. JONES: That's all I'm trying to figure out is what photomicrographs Dr. Weber has actually seen because she can't identify them for me. MR. SLATER: Dr. Welch had those
2 3 4 5 6 7 8 9	Dr. Provder; is that correct? A Mr. Provder, yes. Q And did you rely upon the report of Dr. Serrato in formulating your opinions? A Yes. Q Did you review the ultrasounds that Dr. Serrato performed? A No. Q Have you ever seen any ultrasounds on	2 3 4 5 6 7	Dr. Welch's report was produced, we gave you all of the photomicrographs of every single slide he looked at and those were provided to Dr. Weber. MS. JONES: That's all I'm trying to figure out is what photomicrographs Dr. Weber has actually seen because she can't identify them for me. MR. SLATER: Dr. Welch had those prepared in his offices at Harvard and then they
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Page 294 Page 296 And the numbers, I don't have the A Can you help me understand what you mean 1 1 2 list of materials reviewed, but I assume the list of 2 by a diagnostic conclusion? Q For what purpose did you look at the 3 numbers is the numbers from the institutions where 3 4 they identify the path slides. I mean, they have 4 photomicrographs? 5 5 section numbers, whatever you call them. A To correlate them with the findings of 6 BY MS. JONES: 6 Dr. Welch. 7 Q So that what we're clear on, Doctor, is 7 Q Of Dr. Welch? 8 that the photomicrographs you have gotten are the 8 Dr. Welch. 9 ones from Dr. Welch? 9 THE WITNESS: Did I speak correctly? 10 MR. SLATER: Yes. 10 MR. SLATER: Yeah. 11 MS. JONES: Not from any other 11 BY MS. JONES: institution, not prepared by any other institution? 12 12 Q Prior to receiving the report of Dr. Welch That was my question. 13 13 and the photomicrographs, had you looked at any of MR. SLATER: To my knowledge, there the pathology for Ms. Gross? 14 14 15 are no other photomicrographs. 15 Α No. MS. JONES: That's the reason I'm 16 16 Q Had you expressed any opinion with respect asking the question. to the pathology for Mrs. Gross prior to seeing 17 17 18 MR. SLATER: Do you have any that I 18 Dr. Welch's report? don't know of? Want to throw all our chips into the 19 19 A No. 20 middle of the table? No, I'm not aware of any. In 20 Is it a fair assumption that you rely upon 21 fact, I just e-mailed my partner to find out if the 21 Dr. Welch for any of your opinions with respect to defense experts prepared any photomicrographs on the 22 22 the pathology? slides they looked at because I don't think we were 23 23 Α Yes. 24 produced any. So I actually just e-mailed Dave 24 Q So that you don't have independent Mazie to find out because I don't think we got any 25 25 opinions on the pathology beyond what Dr. Welch Page 295 Page 297 from the defense. They may not have prepared any. 1 reported? 1 I'm assuming they did; otherwise, there's no way to 2 2 Correct. show them to the jury. 3 3 0 And is the same true with respect to MS. JONES: I think we're clear on 4 4 Dr. Serrato? 5 this now. That's all I want to know is what it is 5 A With respect to the ultrasound findings 6 the doctor has seen. 6 you mean? 7 7 MR. SLATER: The photomicrographs --0 Yes. what happened was recuts were provided to Dr. Welch. 8 8 Yes, correct. Α 9 He looked at them. He had micrographs prepared. I 9 Q And is there anything in Mr. Provder's 10 don't know the process. It's some sophisticated 10 report upon which you rely in forming your opinions? camera on a microscope or something probably. I can Yes. 11 11 Α barely work my own camera. And then whatever he 12 What is that? 12 prepared was sent to us electronically, provided on 13 13 On his assessment of her level of disks, we copied the disks, we provided that all to 14 14 disability and inability to return to her 15 you. And whatever we were provided by Dr. Welch, we 15 profession. bounced it to Dr. Weber so she had what we had. Q And you understand that she is a nurse by 16 16 BY MS. JONES: 17 17 profession? 18 Q And you have not seen anything other than 18 A I understand that. the photomicrographs --Would you agree that pudendal neuralgia is 19 19 20 A Correct. 20 a pain syndrome? 21 -- with respect to the pathology? 21 Yes. Α And, Doctor, have you attempted, based 22 22 Can you tell me what the symptoms of upon those photomicrographs, to look at it and come pudendal neuralgia are? 23 23 to any diagnostic conclusions based upon review of 24 24 A There are several characteristic symptoms 25 those photomicrographs? 25 that will vary from patient to patient. Pain in the

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distribution of the pudendal nerve, pain that's worsened with sitting, pain that may be relieved by standing or lying down. That's all.

- Q Are you familiar with a burning sensation being associated with pudendal neuralgia?
- Neuropathic pain is often described by the patient as having a burning character.
 - O How about numbness?
- A Numbness is not strictly a symptom of pain, a characteristic -- a description of the patient's pain experience.
- Q Well, maybe I wasn't clear. I was asking really about symptoms of the pudendal neuralgia.
- A No, I don't think numbness would be a characteristic typical of pudendal neuralgia.
- Are you familiar with feelings of a lump or foreign body in the vagina or rectum associated with pudendal neuralgia?
 - A It can be.

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- Q How about abnormal temperature sensations like flushing?
- A As a response to the pain itself. Maybe you can clarify for me. Are you talking about the symptoms specific to pudendal neuralgia or the symptoms the patient may experience as a result of

How about painful intercourse?

Again, as a result of the distribution of the pudendal nerve in the vaginal area, yes, pain.

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- O How about musculoskeletal pain in other parts of the pelvis?
- 6 A You mean other parts than the distribution 7 of the pudendal nerve?
 - Right, right.
 - Okay. So that answer would be no.
- 10 Would be? Q
 - Α No.
 - So that I understand that last answer, you don't think that pudendal neuralgia is or can be accompanied by musculoskeletal pain in other parts of the pelvis?
 - A Well, let me see if I can clarify that. The pain of pudendal neuralgia can lead to pelvic muscle spasm. And pelvic muscle spasm can occur on both sides of the pelvis, the side on which the pudendal neuralgia exists and also on the other side.
- 22 Can you see pudendal neuralgia and pelvic floor dysfunction together? 23
- 24 A Well, what do you mean by "pelvic floor dysfunction"? 25

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the pain of the pudendal neuralgia?

- O I'm really just talking about symptoms that have been reported in association with pudendal neuralgia.
- A Okay. So, no, I would say apart from an association or an event associated with the patient's pain, an abnormal flushing feeling would not be a typical symptom of pudendal neuralgia.
 - Q How about constipation?
- Again, not specific as a typical symptom confined to pudendal neuralgia itself.
- O How about pain or straining with bowel movements?
- A Well, that is in the distribution of the pudendal nerve so that would be consistent, not straining per se but pain.
- Q How about straining or burning with urination?
- A It's possible, again, with the distribution of the pudendal nerve.
- Q How about a sense that the bladder is not empty or never empty?
 - Again, possible based on the distribution.
- How about low back pain? Q
 - No, I don't think that would be typical. Α

Page 301 Q Well, I said that because I was listening

to you talking about pelvic spasms. If you had some dysfunction of the pelvic floor musculature, could 3 4

you see that in conjunction with pudendal neuralgia?

- And in the course of your practice, Q
- Doctor, did you regularly treat pudendal neuralgia? Α
- If somebody came in with what you diagnosed as pudendal neuralgia, would you refer
- them out? I would evaluate the patient from a
- 13 urogynecologic perspective and offer the patient what I felt was appropriate on that basis. If I 14
- 15 felt that there were contributors or possibly the
- entire etiology outside of my scope of 16
- urogynecology, then I would either -- if I felt 17
- 18 there was a contribution, I would refer her and work
- in conjunction with the referring -- with the doctor 19
- 20 to which I would refer her. If I felt it was entirely outside the scope of urogynecology, then I 21
- 22 would simply refer her.
- Q What is your understanding are the causes 23 24 of pudendal neuralgia? 25
 - A Well, there are several: Trauma; in some

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people situations where they are sitting specifically, for example, on a bicycle or a motorcycle, whether it's the pressure of them sitting on that position or the vibration, say, of a motorcycle engine, there is that association; surgery, of course.

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examination.

- Q We talked earlier already about different forms of prolapse surgery that might be associated with pudendal neuralgia, but has hysterectomy been associated with pudendal neuralgia?
 - A No, hysterectomy by itself, no.
- Q What about childbirth or difficult deliveries?
 - A Yes, that would be possible.
 - Q Infections in the pelvic floor?
- A Infections in the pelvic floor? You mean --
 - Q Or infections in the pelvis.
- A In the pelvis. No, I have not heard that as being a cause of pudendal neuralgia.
- Q And when a patient presented to you with symptoms that you thought might indicate pudendal neuralgia, how would you go about making that diagnosis?
- A I would obtain her history, see if there

1 experiences pain relief. It's diagnostic in the

2 sense that if she experiences pain relief, that's a

very strong indication, what many doctors feel isthe strongest indication, that you are, in fact,

4 the strongest indication, that you are, in fact, dealing with pudendal neuralgia; and then

therapeutic obviously in the sense that if her pain is relieved, she feels better.

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- Q And did you actually when you were practicing perform pudendal nerve blocks?
- 10 A Not in my -- during my residency, yes; not 11 since then.
 - Q During your residency between '88 and '92?
- 13 A Correct
- 14 Q Would that have been the last time that 15 you've treated pudendal neuralgia?
 - A Yes.
 - Q Other than the nerve block, is there any other type of treatment that you would have prescribed for pudendal neuralgia that you can remember?
 - A I would not. At that point I would involve another physician with expertise.
 - Q In the case of Ms. Gross, is it your opinion that the surgery that she had for prolapse caused the pudendal neuralgia or is it the use of

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- were any identifiable factors that may have causedor contributed to this situation. I would ask her
- 3 for a very detailed explanation or description of
- 4 her pain: The location; any factors that relieved5 it or exacerbated it; the nature of the pain, any
- 6 describing words that she could give me; the
- 7 duration; a complete history related to the pain;8 and then any other points of her history that could
- 9 potentially be relevant; and then an examination in 10 the pelvic area to map the distribution of her pain
- to see if it was consistent with the distribution ofthe pudendal nerve; and then an external examination
- to see if that reproduced her pain or exacerbated
 it; and then an internal examination to see if there
 was any other information that I could gather as to
 the location or the reproducibility of the pain with
 - Q And what type of treatment would you prescribe?
 - A Again, this is where -- once I had a better understanding of the possible cause where I would be likely to involve a second physician. A pudendal -- a nerve block -- I could administer a pudendal nerve block in the office. And that has both a diagnostic and a therapeutic effect if she

mesh that caused the pudendal neuralgia?

- 2 A I think it is most likely that the 3 pudendal neuralgia was caused by the proximity of 4 the mesh itself. I can't rule out the possibility 5 of a contributing factor that occurred during the 6 surgery.
 - Q And can you tell me why you think it is most likely to be the proximity of the mesh itself? The proximity of the mesh to the nerve?
 - A Correct.
 - Q And why do you reach that conclusion?
- 12 A I am not sure I understand your question.

13 Why --

- Q Why is it that you believe that it's the proximity of the mesh to the nerve that's caused the neuralgia as opposed to the surgery itself?
- A I think if Mrs. Gross had had a direct very traumatic injury, such as the trocar passage through the pudendal nerve, that would have been immediately evident when she was woken from anesthesia. I think it's possible that she had a less severe injury due to trocar passage. As I said, I can't rule that out.

After surgery then it's the mesh placement, the inflammatory and foreign body

Page 306 Page 308 reaction that it causes, the fibrosis and scarring any way? 1 1 2 in very close proximity to the nerve, if not on the 2 His surgical technique was not incorrect nerve, that led to her pudendal neuralgia. 3 3 based on his operative report. The trocar passages 4 Q And did you review the medical records of 4 themselves introduce an unreasonable degree of risk 5 Ms. Gross to determine whether or not she had 5 of nerve damage specifically along with other types experienced any signs or symptoms before the surgery of damage in the Prolift® procedure. 6 6 7 that might be indicative of pudendal neuralgia? 7 My understanding, though, from what you 8 8 testified earlier, and I'm just asking, is that if Ms. Gross had experienced nerve damage as a result 9 Q Did you find any? 9 of the use of the trocars, you would have expected 10 Α No. 10 11 So when you went back and looked at the 11 to have seen that immediately? Q records, you did not find that she had experienced A Direct severely traumatic as in driving 12 12 any symptoms that had been associated with pudendal the trocar right through the nerve. Also, the 13 13 pudendal nerve at various places, because everyone's 14 neuralgia? 14 MR. SLATER: You're talking about anatomy is different, branches into its three 15 15 prior to the surgery? terminal branches. It's possible that one of the 16 16 smaller branches was directly injured. As I said, I 17 MS. JONES: Prior to the surgery. 17 18 THE WITNESS: I didn't find any 18 cannot rule it out. evidence that she had symptoms of pudendal neuralgia 19 Q I understand that you can't rule it out. 19 20 before the Prolift® surgery. 20 But am I correct that even though you say you can't 21 BY MS. JONES: 21 rule it out, your belief and position as you sit here today is that the nerve damage was not as 22 Q Did you find that Ms. Gross had a prior 22 history of stress urinary incontinence? likely due to the trocar as it was to the placement 23 23 24 A Yes. 24 of the mesh? 25 Q Of obstructed defecation? 25 A Correct. Page 307 Page 309 Those were her symptoms, yes. 1 Is this a good time for a break? 1 2 2 Q And had a rectocele? (Discussion off the record.) 3 3 MS. JONES: Can we go ahead until we Α Yes. 4 Q Ms. Gross had also had several 4 get lunch? 5 pregnancies, had she not? 5 THE WITNESS: Yes. 6 6 BY MS. JONES: Three. Α 7 7 There were some difficult deliveries? Q Are you aware, Doctor, of any place in the 8 medical records where there's any mention or What do you mean by "difficult"? 8 9 Q Well, she had a fourth-degree vaginal 9 discussion of pudendal nerve damage prior to August tear, didn't she? 10 of 2007? 10 A Actually in reading the doctor's delivery 11 11 Α Can I look at my report, please? note, he cut the fourth-degree to make room for the 12 12 13 delivery of the fetus. 13 MR. SLATER: Yeah, sure. I have it Q Had she had any pelvic spasms of which 14 14 on the floor here. 15 you're aware? 15 BY MS. JONES: A Pelvic muscle spasm? Q Doctor, I'll tell you where I think it is. 16 16 I picked that up on Page 6 of your report. And my 17 Q Uh-huh. 17 18 No, not to my knowledge. 18 note says the first mention of pudendal nerve damage Α Q So do I understand your opinion, Doctor, as a cause of the symptoms was recorded on 19 19 to be that Dr. Benson's use of trocars in the 20 August 29th, 2007. 20 A Okay. And that's on Page 6? Prolift® surgery did not likely cause the pudendal 21 21 O I have it marked on Page 6. That's what I 22 nerve injury? 22 A I can't rule it out. 23 took my notes from. 23 24 Q Do you have any opinion as to whether or 24 THE WITNESS: Can I ask you a not Dr. Benson's surgical technique was incorrect in 25 question? Should we step out or can I just ask you? 25

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          MR. SLATER: No. Don't ask me
anything. I mean, if there's something missing from
this notebook, then I have to just get someone to
bring it in. The page number may just be a typo or
something on her outline.
          MS. JONES: It may be. I promise
this is not a trick. I have my notes.
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THE WITNESS: Yeah, I just -- I don't see what you're saying.

10 BY MS. JONES:

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Q I don't see it on Page 6 either. I've obviously got a typo on it.

> MR. SLATER: Off the record. (Discussion off the record.)

BY MS. JONES:

- Q All right. Doctor, while we were off the record, it is on Page 5 that you note in your report that the first mention of pudendal nerve damage as a cause of Ms. Gross' symptoms was on August 29, 2007; correct?
 - A Correct.
- O And you mentioned that you had treated pudendal neuralgia in your residency. Was it in medical school or in the residency that you were taught the distribution of the pudendal nerve?

think I caught the last of what you said about how it could -- I know we talked about the approach, but tell me how it entraps the nerve.

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- A So the superior surface of the sacrospinous ligament, the ischial spine, and the pudendal nerve are all in very close proximity. The surgeon in passing a suture through the superior aspect of the sacrospinous ligament may inadvertently include the pudendal nerve in that suture, entrapping it. It's called pudendal nerve entrapment.
- Q And it's that type of entrapment that's generally the cause of pudendal nerve neuralgia in the sacrospinal ligament fixation surgery?
 - A Correct.
- Q The surgery that Ms. Gross had on the pudendal nerve was in June of 2009; correct?
- Q And it was performed by Dr. Hibner?
- 20 Α
- 21 At the time that Dr. Hibner performed that Q 22 surgery, he did not find the presence of mesh, did 23 he?
 - There's conflicting information on that point. The operative note which he dictated

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Both.

Α O And were you taught to do the pudendal nerve block in your residency or in medical school?

A I certainly learned it in my residency. I don't remember if I learned it in medical school also.

- O You testified earlier that pudendal nerve damage can be the result of the sacrospinal ligament fixation?
 - A Correct.
- Q And my question is, how is it caused by that surgery?
- A Typically it's an entrapment where the suture -- in a sacrospinous ligament fixation, the surgeon is approaching the sacrospinous ligament from its superior aspect. And the pudendal nerve in relation to the ischial spine and the sacrospinous ligament is in very close proximity in such a way that a suture can be passed into the substance of the sacrospinous ligament and entrap the pudendal nerve.
 - Q Would you say that again, please?
 - Do you want me to rephrase it or --
- No, no, no. I just -- I think my mind went in and out just for a second. I just don't

immediately after performing the operation has a description of mesh attached directly to the pudendal nerve. Under testimony Dr. Hibner testified that he did not believe it was mesh; if it were mesh, he would have sent it for pathology, and he did not send it for pathology and he believed it was scar tissue.

Now, in terms of causing Mrs. Gross' pudendal neuralgia, whether it was mesh or not, according to Dr. Hibner's conflicting information, she had pudendal neuralgia on the basis of the mesh implantation near or -- adjacent to or touching the pudendal nerve in such a way that the inflammatory body reaction, the scarring, the fibrosis from the Prolift® mesh implantation was responsible for her pudendal neuralgia.

- Q Have you seen any pathology that shows that mesh is in any of the scar tissue around the pudendal nerve?
- A As I understood from Dr. Hibner's testimony, he did not send that specimen for pathology.
- Q And you've not seen any pathology from any other surgery or any other findings that mesh was actually removed from the pudendal nerve?

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A Again, to my understanding from Dr. Hibner's testimony, that wasn't sent for pathology. You wouldn't take -- even if he had taken mesh off the pudendal nerve, unless he excised the pudendal nerve or a part of it, that would not show up in the pathology specimen.

Q You wouldn't send an encased mesh to pathology?

A According to my understanding of the operative note, mesh or scar -- mesh, that's in the operative note, Dr. Hibner's testimony, scar tissue was found attached to the pudendal nerve. The goal of the operation, of course, is to leave the pudendal nerve intact. If you excise a portion of the pudendal nerve and send it to pathology, the patient is obviously going to suffer from that excision.

Q My question was really a little different, Doctor. If you as a surgeon excised tissue in which mesh was encased, would you have sent that to pathology?

A Yes.

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Q And would you think that that would be the standard of care for a surgeon to send that material to pathology?

Dr. Benson performed a surgery to excise the Prolift® vaginal mesh; correct?

A To my understanding, he was concentrating 3 4 on the anterior portion of the Prolift® mesh at that 5 surgery. 6

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Page 317

Q And subsequently Ms. Gross had other portions of the Prolift® removed; correct?

9 0 Did Ms. Gross suffer from interstitial cystitis? 10

In my opinion, no.

What's that opinion based upon?

That opinion is based upon the -- my understanding of the course of interstitial cystitis and how that did not match up with Linda Gross' course.

O Tell me what you understand the typical course of interstitial cystitis to be.

A Well, first I'll explain interstitial cystitis is a collection of symptoms. In its severe form that leads to cystoscopic findings, it is a chronic disease or condition with symptoms of urgency, frequency, and bladder pain that occur over the course of months and years.

Mrs. Gross didn't have a diagnosis of

Page 315

A I was taught to send all material to pathology. You take it out of the patient, you send it to pathology. I can't really speak to what every other surgeon does.

Q That's what you would have taught your residents and fellows when you were involved in academic medicine?

A Correct.

Q I take it that it's your position that Ms. Gross would not have had pudendal nerve neuralgia but for the use of Prolift®?

Correct.

Have you seen any medical literature specifically that relates to Prolift® and pudendal nerve involvement?

Α No.

Mrs. Gross had mesh removed and the Prolift® removed in early 2007, did she not?

MR. SLATER: Objection to the form. You can answer.

THE WITNESS: The date again, please? BY MS. JONES:

Q I confess to you, Doctor, I'm looking for the exact date. I don't have it in my notes.

In December, December 14 of 2006,

1 interstitial cystitis before she had the Prolift®

2 placed. I believe it was approximately two months

3 after the Prolift® procedure Dr. Benson performed a cystoscopy and described findings that he attributed 4

5 to the possibility of interstitial cystitis. On

subsequent cystoscopies those findings were not 6 7 repeated. 8

So on that basis she didn't have it

9 before, she had one cystoscopy two months after the 10 surgery at a time when she was experiencing urinary 11

tract infections, retention -- and urinary

retention, and the cystoscopic findings were never 12 13 seen again on subsequent cystoscopies.

Q You told us yesterday that you had spoken 14 15 with one of the other plaintiffs' experts with respect to interstitial cystitis; am I correct? 16

A Yes.

Q And who was that?

19 That was Dr. Elliott.

20 Q And did you speak with Dr. Elliott

21 specifically about the diagnosis of interstitial

22 cystitis in Ms. Gross? 23

I can't remember.

24 Does Dr. Elliott, if you know, have a more 25 extensive background in the treatment of

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Page 318 Page 320 interstitial cystitis in women than you do? causative or contributing factors that could be 1 1 2 A Yes, I would presume so. 2 addressed by behavioral or lifestyle changes, if 3 Q In your practice, Doctor, did you something was triggering the pain specifically. If 3 4 regularly treat women with interstitial cystitis? 4 there weren't any known triggers that I could 5 5 address, then it's empiric treatment for muscle 6 relaxation. I would start with physical therapy. I 6 Q Do you know how many women you actually 7 treated with interstitial cystitis? 7 would add pharmacologic therapy if needed. 8 8 O And would you follow the same process with 9 Q After you completed your residency, did 9 respect to myofascial pain? you treat anyone with interstitial cystitis? 10 10 A Myofascial pain is -- myofascial pain is 11 A I'm sure I saw patients with a history of 11 used synonymously with pelvic muscle spasm. stable interstitial cystitis. I did not treat With muscle spasms? 12 12 patients with bladder distillation or Pelvic muscle spasm, hypertonicity, 13 13 levator myalgia. There isn't one name for this 14 hydrodistention or any other form of that kind of 14 15 treatment. 15 condition. 16 Q And would you regularly refer people with 16 Q I understand. When you said synonymously, those conditions to urologists? it threw me off a little bit, because I thought you 17 17 18 A Yes. 18 said that muscle spasms were synonymous with Q Are there sources of inflammation in the myofascial pain. Maybe I misunderstood. 19 19 20 pelvic floor other than mesh, for example? 20 A Well, myofascial pain is not specific. A In the pelvic floor? 21 That could be any muscles in the body. So are you 21 22 Uh-huh. 22 talking about pelvic myofascial pain? Q O I am. 23 The pelvic musculature? Source of 23 Α inflammation. Certainly, muscles can be inflamed 24 A Okay. So then it's possible you could 24 for reasons other than mesh. 25 25 have pelvic muscle spasm without pain. But if you Page 319 Page 321 Q For example, could you have inflammation 1 have pelvic muscle spasm and pain, that would be 1 2 associated with muscle spasms or tension? And let 2 used interchangeably with pelvic myofascial pain. Q Are there other sources of pelvic me say muscle spasms or tension in the pelvic floor 3 3 muscles, the musculature. myofascial pain other than muscle spasms? 4 4 5 A So are you asking whether inflammation is 5 A Sure. Anything that can happen to a the starting point and then it's associated with the muscle. You can strain it. You can bruise it, I 6 6 7 development of pelvic muscle spasm? 7 suppose. You could -- it could be traumatized in 8 Q No. I'm asking whether or not muscle 8 some way. spasms or tension in the pelvic floor muscles can be 9 Q Can stress trigger myofascial pain? a source of inflammation, can lead to inflammation. 10 Α Like emotional stress? 10 MR. SLATER: Are you talking about Q 11 11 Yeah. 12 generalized inflammation or any particular 12 As opposed to physical stress? Well, physical stress could obviously 13 inflammation? 13 14 MS. JONES: Just inflammation. 14 trigger it; right? 15 MR. SLATER: Objection. 15 Riaht. Α Q Could emotional stress? 16 You can answer. 16 Emotional stress. It could certainly 17 THE WITNESS: Not to my knowledge. 17 18 BY MS. JONES: 18 exacerbate it. It could trigger it if a woman for some reason was adding an element of voluntary 19 Q During the course of your practice, 19 Doctor, did you treat patients with pelvic floor contraction -- muscle tension, of course, anywhere 20 20 is a very common reaction to stress so I don't see 21 muscle pain? 21 22 Yes. 22 any reason why it couldn't affect the pelvis. Α Q And what type of treatment did you Q Is it your opinion, Doctor, that Ms. Gross 23 23 benefited from pelvic physical therapy? 24 prescribe for those patients? 24 25 A Well, in her history I would look for any 25 A After her surgery to treat her pelvic

	Page 322		Page 324
1	muscle spasm? Is that what you're referring to?	1	your counsel has just provided, you have been paid a
2	Q No. You know that she did receive some	2	total of \$328,647 as of October 15, 2012; correct?
3	physical therapy and pelvic floor tone and	3	A I have no reason to doubt the document. I
4	relaxation physical therapy, do you not?	4	do not know the number off the top of my head.
5	A Yes. So that would be after her surgery	5	MR. SLATER: I can represent to you
6	to treat her pelvic muscle spasm; no?	6	this was the accurate number as of the date of
7	Q And it was recommended that she	7	disclosure. There have been subsequent invoices;
8	participate in a pain management program, wasn't it?	8	it's just not updated.
9	A That was offered to her as an option.	9	BY MS. JONES:
10	MR. SLATER: Just so you know, lunch	10	Q Have there been subsequent invoices since
11	is here.	11	October 15?
12	MS. JONES: Okay.	12	A Yes.
13	BY MS. JONES:	13	Q How frequently do you invoice plaintiffs'
14	Q Is it your judgment that she would benefit	14	counsel?
15	from participation in a pain management program?	15	A Once a month.
16	A I don't know.	16	Q What was the date of the last invoice?
17	MS. JONES: Let's stop and have	17	A November 1st.
18	lunch.	18	Q Do you know for what amount that was?
19	(Luncheon recess taken from 1:13 p.m.	19	A I don't.
20	to 2:34 p.m.)	20	MS. JONES: Counsel, can you tell me?
21		21	MR. SLATER: I can find out. I don't
	(Exhibit No. 1220 was marked for		
22	identification.)	22	know off the top of my head, but I'll find out the
23	BY MS. JONES:	23	amount.
24	Q We have marked as Exhibit 1220 the list of	24	BY MS. JONES:
25	materials reviewed. Doctor, have you reviewed this?	25	Q This indicates that your hourly rate
	Page 323		Page 325
1	A Have I reviewed that document?	1	became \$350 an hour in July of 2012; is that
2	A Have I reviewed that document? Q Yes, ma'am.	2	became \$350 an hour in July of 2012; is that correct?
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	Page 326		Page 328
1	A No.	1	Q So that would have been roughly ten and a
2	Q So that remains \$250 an hour?	2	half hours?
3	A Yes.	3	A Yes.
4	Q What prompted you to change this rate to	4	Q And today did you work any before you came
5	\$350 an hour?	5	here for the deposition?
6	A I felt with my growing experience and	6	A Yes. I worked this morning for about an
7	expertise over the past almost three years of	7	hour.
8	reviewing the documents and so on that that added	8	Q And how do you charge for your travel?
9	experience increased the value of my time.	9	A We haven't discussed that yet.
10	Q At any time, Doctor, have you totaled the	10	Q You expect your expenses to be reimbursed,
11	amount of the invoices to confirm that what you've	11	I assume?
12	been paid is \$328,000-plus?	12	A Yes.
13	A No.	13	Q And you expect to be compensated for your
14	Q Since October 15 approximately how much	14	time and travel?
15	time have you spent in this litigation?	15	A Yes.
16	A Not including the time since I arrived in	16	Q Before we took a lunch break, we were
17	New Jersey?	17	talking about whether or not Ms. Gross would benefit
18	Q Well, let's divide it up. Before you	18	from a pain management program. Do you remember
19	arrived in New Jersey.	19	that?
20	A I would say between 30 and 40 hours.	20	A Yes.
21	Q Since October 15th?	21	Q Have you seen or do you know of the
22	A I don't like to guess.	22	success of programs such as the Mayo Pain Clinic
23	Q My recollection is that you testified	23	program in treating pelvic pain?
24	yesterday that you had spent approximately 30 hours	24	A I do not know.
25	a week the last several months preparing for this	25	Q Do you believe that Ms. Gross would
	D 227	T	D 220
1	Page 327	1	Page 329
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2	deposition and the reports and so forth. A Well, I'm still guessing, but a better	2	benefit from pain management? A Are you referring specifically to this
2 3	deposition and the reports and so forth. A Well, I'm still guessing, but a better guess would probably be between 50 and 60 hours.	2	benefit from pain management? A Are you referring specifically to this program now or pain management in general?
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what additional consultations would be beneficial in her overall management. And I would go from there.

Q As you sit here today, do you have any opinion as to what other consultations would be beneficial to her in her overall management?

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- A She has a pain management specialist. She has her family practitioner. She sees urogynecologists. She's receiving psychological counseling. She sees a urologist. She undergoes physical therapy. I can't think of any other consultations that I could offer her at this time.
- Q Is there any medical treatment that you as a urogynecologist would offer her today?
- A Well, to the extent possible, considering her conditions are now more likely than not permanent, I think she's receiving the -- unless something new happens, her current management I think is addressing all of her issues and offering her what there is available, although limited, because she's not in a state where cure is a possibility for her, she's in a state of palliation.
- O What is your prognosis or what is your opinion as to her prognosis if you have one?
- Specific to any one of her conditions or all of them?

Q Is there anything other than the ultrasounds upon which you rely for your opinion that there are some residual pieces of mesh?

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Page 333

A To my understanding of the operative reports, specific areas, such as the placement of the two superficial anterior arms through the obturator space and the two deep anterior arms through the obturator space and the two posterior arms through the ischiorectal fossa, have not been specifically sought with the idea of removing them.

In fact, Mrs. Gross has been informed that it would be -- it would introduce additional morbidity. And her husband, Mr. Gross, had a very insightful observation: If it's too difficult to remove the mesh that was implanted, how is -- or too dangerous, how is it not too dangerous to implant it in the first place?

MS. JONES: Move to strike as nonresponsive.

19 20 BY MS. JONES:

- Q Are you relying upon his deposition or have you spoken with Mr. Gross?
 - A I have not spoken with Mr. Gross.
- Have you reviewed the reports of the defense experts with respect to Ms. Gross?

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- Q To any condition about which you've been asked to opine.
- A I believe that her condition, while it may wax and wane within a certain restricted range over time, is otherwise permanent.
- Q And when you say her condition is permanent, will you describe for me what condition it is that you believe is permanent?
- A I believe her pain is permanent. It's possible she may experience some relief, not likely resolution of the pelvic muscle spasm component of her pain. I believe her urinary retention is permanent and she will require intermittent self-catheterization for the rest of her life. To the extent that she has mesh remaining, she remains at lifelong risk for mesh-related complications like mesh erosion.
- Q Do you have any evidence that she, in fact, has mesh remaining in her body?
- A To my knowledge, there are at least pieces of the six mesh arms that were implanted in Linda.
- O And have you done anything in any way to quantify the amount of mesh, if any, that's left?
- A No, that's not possible. Ultrasound can visualize mesh -- can visualize mesh.

1 Α Yes.

- 2 Which reports have you reviewed?
- Kavaler, Minkin. I believe those are the two that are specific to Mrs. Gross. 4
 - Do you have any opinions or disagreements with either of those reports?
 - A Yes, I do.
 - Q Can you tell me what they are?
 - Can I have the report, please?
 - If you have it with you.

MR. SLATER: Well, I can go have somebody print copies. You don't have them?

MS. JONES: I'm asking for the

disagreements with the report.

MR. SLATER: I understand. She's

saying she needs to be able -- they're lengthy 16 reports. What she's going to likely do now is go 17

- 18 page by page for probably an hour or two. I'm not
- 19 being facetious. I can go get them printed, but if 20
- the question's going to be to list all her
- 21 disagreements --
- 22 BY MS. JONES:
 - Q Have you, in fact, prepared a report
- 24 listing all your disagreements? 25
 - A I have made comments.

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Page 334
                                                                                                            Page 336
        Q Where did you make comments?
                                                               you're going to ask someone about a document, give
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                                                           1
2
        A In a document.
                                                           2
                                                               it to them and say, here, I'm going to ask you some
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        Q In what document?
                                                               questions about the document.
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        A I don't remember the title. It's not a
                                                                         So we'll take a break. I'm going to
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                                                           5
                                                               go get those two reports. And, counsel, you have
    report as in those reports of mine.
        Q It's not a report that's been furnished to
                                                               the materials reviewed. You know that she saw all
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    us?
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                                                               the expert reports. It's all listed. I'll go get
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                                                               those two reports because that's your particular
        Α
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        Q Let me ask you, Doctor, to summarize if
                                                           9
                                                               question. It's actually three reports. Take a
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    you can your disagreements with those of
                                                          10
                                                               break while I get them.
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    Dr. Kavaler.
                                                          11
                                                                         (Short recess.)
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        A I really prefer to have the report in
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                                                                         MR. SLATER: So I have given her the
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    front of me.
                                                          13
                                                               reports now.
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              MR. SLATER: I'm going to go get
                                                          14
                                                               BY MS. JONES:
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    someone to print it.
                                                          15
                                                                   Q Okay. I have a question before you go
                                                               through the reports, Doctor. You said that you had
16
              THE WITNESS: Because my criticisms
                                                          16
    are very specific and I'll do a much better job when
                                                               prepared a document critiquing these reports for
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                                                          17
18
    I have the report in front of me.
                                                          18
                                                               Mr. Slater?
    BY MS. JONES:
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19
                                                                   A Yes.
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        Q So as we sit here today, you really don't
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                                                                   0
                                                                      Did you review that report in preparation
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    remember what those criticisms are?
                                                               for this deposition?
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              MR. SLATER: That's unfair. I
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                                                                         MR. SLATER: Objection to the form.
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    object. You asked her to list her criticisms. And
                                                          23
                                                                         You can answer.
    any competent and reasonable witness and attorney
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                                                                         THE WITNESS: Considering the defense
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    would want to have the document in front of them in
                                                               expert reports were only served on October 15th, it
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                                                          25
                                                 Page 335
                                                                                                            Page 337
    order to answer the question when Kavaler's report
                                                           1
                                                               has been in the past couple of weeks. I don't know
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    is nearly 50 pages long, Minkin wrote two lengthy
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                                                           2
                                                               that I reviewed it specifically in preparation for
    reports. So she has the right to have the document
                                                               my own deposition.
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    in front of her if you're going to ask her any
                                                           4
                                                               BY MS. JONES:
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    questions about the document; right? So I'm going
                                                           5
                                                                  Q Have you reviewed that document since you
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                                                           6
                                                               arrived here on Saturday?
    to get them.
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              MS. JONES: I'm asking her questions
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                                                                      No.
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    about her opinions, counsel.
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                                                                      When did you actually prepare it?
              MR. SLATER: You're asking what?
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                                                           9
                                                                  Α
                                                                      I don't know. Sometime after
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              MS. JONES: I'm asking her questions
                                                          10
                                                               October 15th.
                                                                  Q Sometime in the last two to three weeks
    about her opinions. I asked her to summarize those
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                                                          11
    opinions. I think I'm entitled to an answer to
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                                                          12
                                                               anvwav?
                                                                  A Correct.
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    that.
                                                          13
                                                                      Now, what I would like you to do is to
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              MR. SLATER: You're going to get an
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    answer. You object to me putting the reports in
                                                          15
                                                               summarize for me your criticisms or disagreements,
    front of the witness?
                                                               however you choose to characterize it, with
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              MS. JONES: I don't have any
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                                                               Dr. Kavaler.
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    objection to it.
                                                          18
                                                                  A A general summary of my opinions is that
                                                               she does not address all the issues of substance,
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              MR. SLATER: So I'll go get them.
                                                          19
20
              MS. JONES: But I think that's the
                                                               she makes misleading and inaccurate statements, and
                                                          20
    reason we ask you to bring documents with you.
                                                               her opinion -- I disagree with the opinion -- her
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                                                          21
              MR. SLATER: Hang on, Hang on, With
                                                               opinions as to the causation of Mrs. Gross'
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                                                          22
    all due respect, you're taking a deposition, you're
                                                          23
                                                               injuries.
23
    asking questions of the witness about documents you
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                                                          24
                                                                  Q
                                                                      Do you know Dr. Kavaler?
    didn't bring. The customary thing that we do is if
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                                                                      No.
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Page 338

Ever met her? Q

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Know anything about her practice beyond what you know in the report?

A I think I Googled her once her report was provided to me.

Q Ever read any of her publications?

When you said that she did not address all 0 of the material aspects of the case, what areas do you believe she failed to address?

A She failed to address, among many other things, Ethicon's failure to warn physicians and patients of the material risks, many of which affected Linda Gross directly, like the risk of urinary retention.

In fact, Dr. Robinson right before he joined Ethicon was so alarmed about the extent and severity of urinary retention that he was seeing in his patients and in other -- the patients of other physicians with whom he was in contact when he first arrived at Ethicon, he felt strongly that he wanted to include a specific warning in the Prolift® IFU about the risk of this prolonged and severe urinary retention.

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exposure -- mesh erosion and recurrent mesh erosion that could not be resolved, vaginal anatomic distortion and scarring that could not be addressed in a way that a woman was able to engage in normal sexual relations, to name a few.

Shall I keep going?

Q Anything else that you believe that she failed to address that she should have addressed in this context.

A She failed to address Ethicon's failure to warn that patients on anticoagulation therapy are contraindicated to undergo the Prolift® procedure. This was another warning that Ethicon had placed in its instructions for use, for example, for the TVT®, which is only two trocar passes, and yet in the Prolift® procedure with six trocar passes through the deep pelvis a warning was not added. It was considered. And Ethicon, for reasons that are inexplicable to me, never made that change.

There was a warning that Axel Arnaud wanted to include in the Prolift® IFU right before Prolift® was getting ready to launch about pelvic pain and pain with intercourse. And this warning was not added to the IFU because the IFUs had already been printed and the change -- Ethicon

Page 339

This was discussed. Opinions from experienced Prolift® users were taken -- were obtained urgently at a meeting. They didn't know what caused this. Ethicon didn't study it. They drafted something to be put into the IFU and it never made it into the IFU. So physicians and patients went unwarned of this severe risk after the Prolift® procedure.

MS. JONES: Move to strike as nonresponsive.

BY MS. JONES:

O Doctor, other than the risk of urinary retention that you believe that Dr. Kavaler failed to address, are there other issues that you believe she failed to address?

MR. SLATER: Objection to the form of the question.

You can answer.

THE WITNESS: She failed to address Ethicon's failure to warn of the risk of complications after the Prolift® procedure that were untreatable. BY MS. JONES:

23

24 Q Such as?

Such as chronic pelvic pain, mesh

Page 341 didn't want to make the change and reprint the IFUs.

1 2 MS. JONES: Move to strike as

3 nonresponsive. BY MS. JONES:

> Q What other areas do you believe -- and I'm just asking you to list them -- that Dr. Kavaler failed to address?

> MR. SLATER: And just for the record, you want her to just go off the top of her head and list generally? She has the report here.

MS. JONES: She's got the report in

front of her. I'm just asking her --

MR. SLATER: You can keep listing off the top of your head and then eventually you can sit down and go through the report if you want to if counsel wants the complete list.

THE WITNESS: One more thing is that Dr. Kavaler failed to address the failure of Ethicon to properly study Prolift® before launch in a way that would allow for appropriate patient selection, and that includes patients with preexisting pain conditions, when it was learned only later that these patients would have an -- or were at higher risk to have an exacerbation of their preexisting

24 25 pain condition or the development of a new pain

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Page 342

condition such that implantation of the Prolift® was 2 contraindicated in them, that they could develop complications that were untreatable, that left them 3 4 with devastating, life-altering complications for which there is no treatment.

Dr. Kavaler failed to address the fact that Ethicon failed to study the complications that were known and foreseeable that would occur with the Prolift® procedure. And they failed to include this in their internal design processes which, if they had performed properly, the Prolift® would have never reached the market.

MS. JONES: Move to strike as nonresponsive.

BY MS. JONES: 15

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- Q Do you know, Doctor, whether or not Dr. Kavaler actually used the Prolift®?
 - A I believe she stated so in her report.
- Q She actually had experience using Prolift® with her patients, did she not?
- A Evidently. I just answered that. I'd like to continue to address your previous question.
 - Q Other things that you say she left out?
- Α The other disagreements I have with her opinions.

Yes. Α

What are they?

A On Page 27, No. 3, Dr. Kavaler claims that Mrs. Gross has recurrent prolapse. She did not have recurrent prolapse. Her opinion is that Prolift® was an appropriate choice to treat her bothersome recurrent prolapse. And, again, she does not have recurrent prolapse.

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Page 345

Prolift® is a safe and effective treatment of pelvic organ prolapse. I do not agree with that.

- 11 Q Let me make myself clear. Maybe my question wasn't clear. The opinion that you have 12 about Prolift® is set forth in your report, is it 13 14 not?
 - Correct. Α
 - Q My question is: Are there any opinions that you have in response to Dr. Kavaler that are not set forth in your report?
 - A Yes.
- 20 That's what I'm trying to identify is just 21 that discrete group of opinions that you have not 22 previously written about.
 - A Okay.

MR. SLATER: Just objection to the form.

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Q Let me separate these if I can, because I thought that we were talking about first and I thought my question was first what is it that you believe that she left out and didn't address, because that was where you started first.

A Well, what you asked me first was what I did I disagree with in her report. And on Page -give me just a second.

Okay. So on Page 69 she is addressing the -- she is addressing -- she's making a counterpoint to my opinion in which she states: Ethicon adequately warns about the risk of nerve damage in its Prolift® IFU and patient brochure.

And in other places in her report she opines that Ethicon's Prolift® IFU adequately warned of the risks. So what I was doing was providing you with my opinion in contrast to that that Ethicon did not adequately warn of the risks in its Prolift® IFU.

So now shall I continue with my disagreements with her opinions?

O I would like to hear all of your disagreements. Before we spend time doing that, let me ask you this: Are there any disagreements with her opinions that are not set forth in your report?

You can answer.

THE WITNESS: Page 27, No. 5: Linda Gross chose to undergo so many surgeries after the

original implant that it is impossible to attribute 4

5 her present condition to Prolift®. Many of these 6 surgeries were against the advice of her

7 physician -- physicians.

This is absolutely unreasonable.

9 Mrs. Gross went through the process of multiple 10 surgeries at each time sitting down with her

surgeon, discussing her condition, and making a 11

joint decision to go ahead with surgery. She didn't 12

set out to have the number of surgeries she had. 13

She had the number of surgeries she had as a direct 14

result of the Prolift® procedure and the permanent 15

Prolift® mesh implantation. At each time she was 16

faced with the decision as to whether she would 17

18 undergo surgery again. This was in consultation

19 with her surgeon and under his or her recommendation

to go forward because that was a reasonable choice

20

at the time. To suggest --21

22 BY MS. JONES:

23 Q May I just ask -- let me just ask one question. 24 25

MR. SLATER: Don't interrupt her. I

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mean, she's in the middle of her answer.

MS. JONES: I just want to ask this question.

BY MS. JONES:

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- Q Is there documentation in the medical records that surgeons advised her against having further surgery?
- A Yes. I would like to expand on that and also complete the answer to the question.
- Q I'm perfectly happy for you to complete your answer.

A It is unreasonable and unethical to suggest that Mrs. Gross underwent surgery at any particular instance because no surgeon acting ethically would perform a surgery that he or she did not feel that the possible benefit of that surgery outweighed the possible risks. It would be unethical to do otherwise. To suggest that Mrs. Gross underwent surgery against the advice of her physicians ignores that obvious and very basic, fundamental aspect of the practice of surgery.

Q Are you finished?

That's the rest of my answer to that question. Shall I continue with the remaining disagreements that I have with Dr. Kavaler that are

Page 348 pudendal -- the pudendal nerve was the surgery that 1

- she had with Dr. Hibner, the neurolysis and the
- 3 combination of procedures that accompanied that.
- 4 It's ludicrous to suggest that pudendal neuralgia
- 5 was the result of that surgery when pudendal
- neuralgia was the indication for that surgery. At 6 7 no other time did Mrs. Gross undergo a surgery that
- 8 directly addressed the pudendal nerve or that would
- 9 place the pudendal nerve at risk for the kind of
- 10 outcome she had, the pudendal neuralgia, except for 11 the indexed Prolift® procedure and the result of the
- 12 Prolift® mesh implantation.

No. 8: Linda Gross' incomplete

14 bladder emptying cannot be attributed to Prolift®. I disagree with that opinion and the basis for that 15 16

is explained in my report.

No. 9: Linda Gross' two mesh 17 18 extrusions are the result of post-implant surgeries, not her July 2006 implant surgery. I disagree with 19

20 this opinion. And, again, it is ludicrous to

21 suggest that mesh erosion as a complication can

22 occur unless you have mesh implantation. She had

Prolift® mesh implantation, and as a result of that 23

24 mesh implantation she subsequently developed the

25 complication of mesh erosion.

Page 347

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not otherwise in my report?

O I thought that that was what you had just told me you had completed.

A That was No. 5. I was just completing my response to No. 5 on Page 27.

O Please tell me what else you disagree with that's not otherwise in your report.

MR. SLATER: Objection to the form.

You can answer.

THE WITNESS: No. 6: Linda Gross' current condition is attributable to pelvic muscle spasms. Dr. Kavaler ignores the reality that Linda Gross has pelvic muscle spasm in addition to other conditions. She acts like pelvic muscle spasm is the exclusive cause of the constellation of Linda Gross' symptoms and I do not agree with that.

Prolift® did not -- this is No. 7: Prolift® did not cause pudendal neuralgia in Linda Gross. If Ms. Gross at some time -- excuse me -- at some point developed a pudendal injury, it cannot be attributed to Prolift®, particularly in light of her preexisting history of pelvic floor defect and her extensive history of post-implant surgeries.

The only surgery that Mrs. Gross underwent that specifically addressed her

No. 10, Page 28: The known risks of Prolift® are adequately warned about in the product's IFU and patient brochure. I utterly disagree with this. In -- I'm going to try to confine my remarks to what is not already in my report at your request. Linda Gross read the patient -- the Prolift® patient brochure and she relied on it in making her decision to go ahead with the Prolift®. She believed the false and misleading statements in the Prolift® patient brochure.

MS. JONES: Move to strike as nonresponsive.

13 MR. SLATER: She's in the middle of 14 her answer.

MS. JONES: I don't care.

16 BY MS. JONES:

Q I mean, I've asked only for an identification of what it is that you disagree with in the report that's not otherwise set forth in your 20 report. And if you disagree with the statement that they failed to warn, that's all I need. 21

MR. SLATER: You realize my concern with the question is it's a very difficult thing to say what's in the report, what's not in the report. You know, we're being cautious because we're

35 (Pages 346 to 349)

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Page 350 Page 352 concerned about someone later saying something fell deposition today, I am going to withdraw my question 1 1 2 within the crack. 2 to ask you to go through and outline the various 3 disagreements with Dr. Kavaler. 3 BY MS. JONES: 4 4 Let me ask you this question: Have you Q Let's answer this question, Doctor: Have 5 5 you set forth in your roughly 600 pages of report reviewed the report of Dr. Minkin? your opinions with respect to the warnings and the 6 6 A Yes. 7 contents of the IFU? 7 Q Have you reviewed the report of 8 8 Dr. Stevens? Yes. Α 9 9 A Yes. Q Have you set forth in your report your 10 opinions with respect to the warnings and content of 10 Q In the document that you prepared with 11 the patient brochure? 11 your comments about these reports for Mr. Slater, did you include in there comments about Dr. Minkin 12 A Yes. I would like to point out you asked 12 me specifically with regard to Linda Gross and with and Dr. Stevens? 13 13 regard to what's not already in my report. I'm A I don't recall making comments about 14 14 telling you about the patient brochure and what Dr. Stevens' report. 15 15 Linda relied on. That's not in my report. Q In your report and opinions we talked 16 16 O Let me ask you this: You're relying upon about, you have said that you believe that Ms. Gross 17 17 18 Ms. Gross' deposition testimony? 18 experienced fear, anxiety, and depression on a permanent basis; is that correct? 19 A Correct. 19 20 So am I allowed to go forward? 20 Α Yes. MR. SLATER: Just hang on. She'll 21 Q Can you tell me what that is based upon? 21 22 ask a new question. 22 Α What my opinion is based upon? 23 THE WITNESS: I thought I was still 23 Q Exactly. 24 answering the last question. I thought I was still 24 Α Yes. answering the question where you asked me --25 25 Q What's the basis for that opinion? Page 351 Page 353 BY MS. JONES: 1 The basis for that opinion is my review of 1 2 O Is it your intent, Doctor, to walk through 2 her medical records and the depositions of her every page and every paragraph that Dr. Kavaler 3 treating physicians. 3 wrote in her report and say you disagree with it? Have you reviewed any medical records 4 4 5 MR. SLATER: Before you answer, I 5 relating to any psychological issues that she 6 have to place an objection. Just one second. 6 experienced before having Prolift®? MR. SLATER: Objection to the form of 7 Counsel, if you ask the question what 7 8 does she disagree with in Dr. Kavaler's report, I 8 the question. 9 assume you'd want her to go through and tell you 9 You can answer. everything, so that's what you would expect her to 10 THE WITNESS: Could you repeat the 10 do. It's a bit argumentative and pejorative to kind question, please? 11 11 of say it as if that's something that you wouldn't 12 BY MS. JONES: 12 expect her to do. 13 13 Q Have you reviewed any records relating to Mrs. Gross' psychological condition prior to the 14 BY MS. JONES: 14 15 Q Do you disagree with every paragraph in 15 Prolift® surgery? Dr. Kavaler's report? Yes. 16 16 Α A I can't make that claim until I, again, go 17 What? 17 0 18 through every paragraph in Dr. Kavaler's report. I 18 Well, for example, when she had her was trying to be responsive to your question and you surgery in 2001, the hysterectomy and Burch 19 19 procedure, she experienced headaches that were 20 interrupted me. 20 spinal headaches, and she had a prolonged course 21 MS. JONES: Let me take 30 seconds. 21 with that that was very distressing to her. 22 (Short recess.) 22 BY MS. JONES: Q Anything else? 23 23 Q Doctor, in the interest of time and Not that I can recall right now. 24 24 Α because I would really like to finish this 25 Q Let me turn to Ms. Wicker for a second. 25

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Can you tell me, Doctor, if Ms. Wicker had presented to you in 2008 when she saw Dr. Bercik, what treatment, if any, you would have recommended for her?

A As we discussed before, I would counsel her regarding behavioral and lifestyle changes, pelvic muscle exercises, pessary use, or surgery. Considering her duration of symptoms was relatively short, I would want to get a better sense from her as to the severity and the impact of her symptoms on her life as we discussed the different treatment options.

After that discussion, if she felt that she would like to proceed with surgery, I would discuss with her the options, with or without a hysterectomy, of apical suspensions such as the uterosacral ligament suspension and the anterior colporrhaphy for her anterior vaginal prolapse.

- Q And do you feel that those surgical procedures would have been appropriate for her condition based upon your review of the medical records?
 - A Yes.

Q Would you have recommended surgery to her for her condition?

Q What do you know about him?

A I know he is the head of urogynecology at Yale. I can't remember anything else specific.

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Page 357

- Q You've already told us that you spoke with Dr. Elliott about whether or not Ms. Wicker suffered from interstitial cystitis I believe?
- A I certainly spoke with Dr. Elliott. I don't remember specifically exactly what we discussed about Mrs. Wicker.
- Q Did Ms. Wicker suffer from interstitial cystitis in your judgment?

MR. SLATER: Objection to the form of the question.

THE WITNESS: That is in her medical history so I would accept her historical report of that, yes.

BY MS. JONES:

- Q Have you attempted to evaluate whether or not there was any other source of pelvic pain for Ms. Wicker other than what you attribute to Prolift® or the Prolift® surgery?
- A Well, at this point Mrs. Wicker also has an element of pelvic muscle spasm which is likely related to her pain, which is due to the Prolift® procedure. Other than that, I don't know that she

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A Well, again, I would want to get a better sense from her -- as I'm sure you can understand, what gets recorded in the medical record is a shorthand for what actually goes on in the counseling session. So what's not present in the medical record are -- is a high level of detail regarding her symptomatic state, the duration of her symptoms, their intensity, her degree of bother related to her symptoms, her impact on her quality of life, and so on. So before I could say with certainty that I would recommend surgery for her, I would need that additional information.

Q Do I understand then that based upon your review of the medical records you can't say one way or another whether or not the surgery was appropriate for her?

MR. SLATER: Objection.

You can answer.

THE WITNESS: Dr. Bercik is an experienced respected surgeon. I am not going to disagree with his decision after he counseled Mrs. Wicker to recommend surgery to her.

23 BY MS. JONES:

Q Do you know Dr. Bercik?

A No.

has any other diagnoses in her pelvis that would account for her symptoms.

Q Pelvic muscle spasms can certainly occur in the absence of the presence of mesh, can't they?

A Yes.

- Q Did you review Mrs. Wicker's medical records for other physical conditions that could account for or contribute to her source of pelvic pain or her pelvic pain?
 - A Yes, I reviewed her records.
- Q Did you identify in reviewing the records any other physical conditions that would account for or contribute to her pelvic pain?

A No, I did not.

Q Based upon your review of the medical records, was there anything in the medical records that should have served as a contraindication to the surgery, the Prolift® surgery, in Ms. Wicker?

A Now there is an understanding that patients with preexisting pain conditions like migraine headaches and interstitial cystitis are contraindicated to undergoing the Prolift® procedure because they have a higher risk of exacerbation of their current condition or the development of a new condition. That information, although known and

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 $${\rm Page}\ 358$$ foreseeable by Ethicon, had not been distributed or

communicated by Ethicon to physicians and patients.

- Q Other than Ms. Wicker's interstitial cystitis, what conditions did you see in the medical records that suggested that Ms. Wicker suffered from any type of chronic pain syndrome?
 - A Migraine headaches.
- 8 Q Anything else?
- 9 A Arthritis.
- 10 Q And where was the arthritis?
- 11 A In her hips.
- 12 Q Anything else?
- 13 A No.

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- Q Was there anything about what you learned from the medical records or the depositions in the case about Ms. Wicker's activities that would have contributed to her chronic pain?
 - A No.
- Q What is your prognosis as we sit here today for Ms. Wicker?

A She carries a lifelong risk of further mesh erosions and requirement -- and the required treatment. She has recurrent prolapse that may or may not be correctable, treatable. She may not be able to undergo surgery for that because of

reported that he had restored the length of the vagina to I want to say 10 centimeters? Does that

Page 360

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vagina to I want to say 10 centirsound right?

- A Yes.
- Q And that Dr. Raz thought he had a good result with that?
- A He had a good result in terms of, as I said, the creation of an anatomic vaginal canal. He was unable to obviously turn back time and give her normal vaginal tissue, vaginal tissue in the absence of fibrosis and scarring and mesh fragments that will continue to pose a risk of recurrent mesh erosion and the need for further surgery and functional aspects of her sexual function in terms of pain, vaginal pain, pelvic pain, pelvic muscle spasm that unfortunately he is also unable to reverse.
- Q And upon what do you rely that she has residual mesh?
- 20 A The ultrasound identification of mesh and 21 the fact that she continues to present with 22 recurrent mesh erosion.
 - Q And when was she last treated for mesh erosion of which you're aware?
 - A In October she had granulation tissue,

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complications from the Prolift®. She has pelvic pain and vaginal pain that more than likely than not is a permanent condition. This affects her ability to have normal sexual relations with her husband in that she has an anatomic vaginal canal, but the dysfunction of the vaginal tissues and the pelvic

dysfunction of the vaginal tissues and the pelvic muscles and the scarring and the fibrosis prevent her from having a normal enjoyable sexual life with

her husband.

Q Let me follow up with some questions on that. First, what surgery, if any, would you recommend be considered for Ms. Wicker to correct

her prolapse?

A That is a very difficult question to answer that Dr. Raz is currently struggling with. She has lost so much of her normal vaginal tissue because of the scarring and the recurrent mesh erosion and the recurrent -- repeated surgeries. I've certainly never faced a situation like that in my clinical experience, so her surgical options in terms of treating her cystocele would have to be

23 (Discussion off the record.)

24 BY MS. JONES:

very creative.

Q Am I correct, Doctor, that Dr. Raz

which in the presence of mesh is often a precursorto the exposure. The last time --

- O October of this year?
 - A Yes. And that was treated in the office.
- 5 Q Was any mesh specifically noted at that 6 time?
- 7 A She did not have an overt mesh erosion.
 - Q Who saw the granulation tissue?
 - A Dr. Raz.
- 10 Q And how was she treated for the
- 11 granulation tissue at that time?
- 12 A She was treated with a topical cautery 13 agent, silver nitrate.
 - O And do you know how she responded to that?
- 15 A I do not.
- Q Do you know whether or not Ms. Wicker is on any pain medication at this time?
 - A I do not know that off the top of my head.
- 19 Q Do you know or have an opinion as to 20 whether Ms. Wicker would benefit from a pain
- 21 management course?
 - A I don't know. She may; she may not.
- 23 Q If she were your patient, would you
- 24 recommend that she receive treatment for pain
- 25 management?

Page 362 Page 364 A And by that -- what do you mean 1 1 A Correct. 2 specifically by "pain management"? She is having 2 Is this a good time for a break? 3 pain management. 3 MS. JONES: We can. I'm trying to 4 Q Based upon what you know of Ms. Wicker's 4 finish. But if you want to take a break, we will. 5 5 current condition, if she came to see you and you THE WITNESS: Yes. examined her, what would you recommend for her, if 6 6 (Short recess.) 7 anything, in terms of pain management? 7 BY MS. JONES: 8 A You mean different or in addition to what 8 O Doctor, have you seen any of the pathology 9 she is currently receiving? 9 on Ms. Wicker? 10 Q Or the same as what she's currently 10 A Yes. 11 receiving. 11 Q What did you see? 12 A Well, she's having physical therapy. She 12 A Photomicrographs of resected tissue and mesh. And I have seen photographs of resected 13 is treated with a muscle relaxant for her pelvic 13 muscle spasm. She is using vaginal estrogen cream 14 14 tissue and mesh. to -- in an attempt to help the vaginal tissue. Q And from whom did those photomicrographs 15 15 She's waiting to see if her vaginal tissue -- she's 16 16 come? waiting to see if enough time can elapse without 17 17 A From Dr. Welch. 18 another mesh erosion for the consideration of 18 Q And from whom did you obtain copies of the treatment of her cystocele. I don't think I have 19 photographs? 19 20 anything to add to that. 20 A From Dr. Raz. 21 Q Other than the interstitial cystitis and 21 Q You reviewed the records relating to Dr. 22 the migraine headaches, is there anything 22 Raz' surgery on Ms. Wicker? significant in Ms. Wicker's preexisting medical A Correct. 23 23 history that's important to you in terms of your 24 Had you ever seen anyone perform a surgery 24 25 opinions? 25 using the materials that Dr. Raz used in the Page 363 Page 365 1 A I consider arthritis as another chronic 1 surgery? 2 2 pain condition that she has. A In -- you're referring to any of his Q Anything else? 3 3 surgeries? 4 Α No. 4 Q Well, you know that he -- these are my 5 Q Do you know what the cause or do you have 5 words, not his words, but did a construct using 6 an opinion of what the cause of Ms. Wicker's polypropylene? Are you aware of that? 6 7 7 The Prolene® suture -prolapse was? Α 8 8 A Well, as I think we discussed previously, Q Yes. the etiology of prolapse is not fully understood. 9 -- is that what you're referring to? Yes. 10 She has some of the epidemiologic risk factors that 10 You know that Prolene® suture is Q have been identified, such as vaginal births. Other polypropylene? 11 11 than those factors, I don't see anything in her 12 12 Α history that stands out in particular. Had you ever seen anyone use that before? 13 13 0 Q Do you have an opinion as to what the 14 14 Α 15 cause of Ms. Wicker's interstitial cystitis was? 15 Q That's not something that you saw or used A Even less so is the etiology of or trained on when you were practicing? 16 16 interstitial cystitis understood. And as I 17 17 A Correct. 18 mentioned before, it's really just a constellation 18 Do you have an opinion as to what the of symptoms. So, no, I do not have an understanding risks, if any, were or are with that procedure using 19 20 of what the cause of Mrs. Wicker's interstitial 20 that material? 21 cystitis is. 21 A Above and beyond or different from the 22 O And I think you told us that rather than 22 risks that we've already talked about in terms of 23 treating a patient with interstitial cystitis, you 23 surgery? would have referred them to a urologist for 24 24 Q Associated with the use of that Prolene® suture as he did. 25 recommendations for treatment? 25

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A It would be possible to have a suture erosion or an uncovering of the suture by -- through or under the vaginal epithelium. That's the only additional risk that I can think of, you know, besides all the other things we've talked about.

Q How would you have counseled your patient on the use of that material in a way different from the use of mesh?

A If a suture erosion occurred, I would counsel the patient that that is a simple problem to solve in that the suture can be simply snipped out. It doesn't involve a dissection. It doesn't involve the likelihood of recurrent mesh erosion. And in general it would be just a much simpler procedure than resecting mesh.

Q As I understand it, Dr. Raz' surgery involved a series of interlocking sutures; is that your understanding?

A Yes.

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Q Have you ever seen any published article on that procedure anywhere using interlocking sutures?

A Not that I can recall. I haven't specifically looked for it.

Q You're not aware of any randomized

patients and his understanding of the risks and 1 2 benefits. In that case I would not consider it 3 experimental.

In the other scenario, I learn about this procedure in some way and I decide I'm going to try it on my patient. In that case it would be experimental and I would counsel her in that way. BY MS. JONES:

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Q Do you know whether or not Dr. Raz had performed this same procedure previously?

I do not know.

12 Q Have you seen any of the radiology in this 13 case?

In Dr. Raz' deposition, images of the ultrasound and MRI were used as exhibits.

O But have you seen those?

A Yes. His deposition was videotaped so, yes, I have seen those.

Q I mean did you just see it on the screen on the videotape or do you have digitalized versions of those materials?

A The former.

23 So you actually watched the video and saw 0 24 those displayed on the screen?

25 A Correct.

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controlled clinical trial using that procedure and those materials?

No. Α

If you had been counseling a patient, would you have suggested to the patient that that would be an experimental therapy?

A Well, as we've already established, I have not been trained in using this procedure. It would depend on what the collective experience had been with that procedure.

Well, I guess my question, Doctor, is knowing what you know today about that procedure and the absence of information about that procedure in the medical literature, would you have counseled or told your patients that it was an experimental procedure?

MR. SLATER: Objection to the form of the question; foundation also.

You can answer.

THE WITNESS: I'll create two scenarios for you. One scenario, let's pretend I'm a fellow with Dr. Raz and I spend three years training with him and I gain from his experience and

skill in teaching and his experience in the performance of this particular procedure with his Page 369

Q You've not looked at them otherwise where you were actually holding them in your hand?

A Correct.

You state in your report that you believe that Ms. Wicker has permanent impairment. Can you tell me what the basis of that opinion is?

A Yes. First I'd like to mention something that I forgot which is relevant to your question, and that is her urinary tract symptoms, which is frequency, urgency, and bladder pain. I believe those symptoms are permanent subject to the management that she's currently receiving.

Q Let me ask you that. Did she suffer those symptoms before she had her Prolift® surgery?

To my understanding, her symptoms related to her history of interstitial cystitis were stable, so she did not have current symptoms related to her history of interstitial cystitis before her Prolift® surgery.

Q Had she had the same symptoms in the past --

22 A I don't believe she --

-- associated with interstitial cystitis?

24 Excuse me. I don't believe she had 25

bladder pain. I believe she had frequency/urgency

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that led to her historical diagnosis of interstitialcystitis.

Q Now, I think you were answering the question of permanent impairment.

A Yes. So her other conditions, her vaginal pain and dyspareunia, I believe those are permanent conditions. Her pelvic muscle spasm contributing to her pelvic pain is undergoing treatment with physical therapy and muscle relaxants. It's possible she may experience some improvement in those symptoms. I am not hopeful that she will experience true resolution.

Q When you're talking about she may experience some improvement in those symptoms, would that be improvement in the symptoms of pelvic spasms and dyspareunia?

A Correct, and vaginal pain.

Q And vaginal pain.

A She has symptoms related to her cystocele. And as I mentioned before, she's waiting -- she and Dr. Raz are waiting to see if a sufficient amount of time will elapse for him to be confident or relatively confident that mesh erosion will not recur and that he may be able to proceed with the

cystocele repair. If he judges that he cannot, then

1 permanent.

Q Can I just ask one question? I asked you first about permanent impairment and then I asked you secondly about disability.

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A Yes.

Q And I'm trying to discern whether or not those are one and the same or they're two different issues. Let me just say if I'm reading this, I look at disability as saying disability in the sense of being unable to participate, for example, in gainful employment or the normal activities to which she has been engaged in. Is that what you're --

A Well --

Q Is that how you would define it, first? MR. SLATER: Objection. You can answer.

THE WITNESS: I would take a broader view of disability affecting every minute of every hour of every day of her life. And that includes, as I said, being disabled in her ability to enjoy normal sexual relations with her husband, being disabled in terms of limitations on her activities based on her frequency, urgency, and bladder pain and the necessary proximity of a restroom and her

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her cystocele will be a permanent condition. She continues to be at risk for recurrent mesh erosion and the risks associated with her treatment, which would be surgical.

Q I'm sorry. You said the risk associated with her treatment would be?

A Surgical.

Q Would be the risk associated with surgery, is that what --

A That's what I intended to mean.

Q I'm sorry. I just didn't understand.

You say in your report that Ms. Wicker is disabled. Can you tell me the basis of your opinion that she is disabled?

A She is disabled to the extent that she can't enjoy a normal sexual life with her husband. She is disabled to the extent that she is troubled by chronic pain and all of the consequences that attend that. She is disabled to the extent related to her urinary symptoms with frequency and urgency and bladder pain that induce anxiety and worry that she will have an incontinent episode in public, for example, and face the humiliation of that if she can't reach a restroom in time. And those conditions, her urinary symptoms, I believe are

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consequences that attend chronic pain and the
disability that inflicts on her quality of life.
BY MS. JONES:

pelvic pain in general and, as I said, the

Q If you were her doctor, based upon what you understand her current condition to be, would you restrict her activities in any way?

A In my opinion, the harm has been done. The harm was done when she had the Prolift® procedure and the permanent Prolift® mesh implantation. I don't believe she can further harm herself by engaging in the activities that provide her with a semblance of the quality of life that she had before.

Q So the answer is that you would not restrict her activities in any way today?

A I would restrict her activities to her tolerance of her symptoms.

Q Can you switch back to Ms. Gross for a second?

A I can.

Q Would you put any restrictions or limitations on Ms. Gross and her activities if you saw her today? A Again, the harm has been done with the

A Again, the harm has been done with the Prolift® procedure and the permanent Prolift® mesh

Page 374 implantation. I don't believe she can further harm herself with her activities. And, again, if -- the restrictions would be only to the -- her tolerance of her symptoms such that she doesn't precipitate a level of pain that's intolerable to her.

MS. JONES: Did someone join us on the phone?

MR. SLATER: I think that was the sound of someone hanging up actually.

MS. JONES: I think it was, too.

That's what I was checking.

MR. CAMERON: This is Roger. I think it was just a line check.

MS. JONES: Dr. Weber, I thank you. I think that's all I have right now.

MR. SLATER: I have a couple brief follow-up questions. I'll only be three or four hours.

19 BY MR. SLATER:

Q A few moments ago in the context of Pam Wicker you were asked about the symptoms of her cystocele, her bladder prolapse that she currently has. Remember that?

A Yes.

Q And within the constellation of symptoms

Q Do you have an understanding of the fact that due to her condition, Linda Gross is unable to conduct her normal daily activities and to work; correct?

Page 376

Page 377

A Yes.

6 Q And that's a result of her condition?

A Yes.

Q It also affects her ability to engage in her day-to-day activities that she would prefer to engage in?

A Yes.

Q You were asked earlier about Dr. Minkin's report about Linda Gross. In her report Dr. Minkin talked about the episode in 2001 where Linda Gross suffered from spinal headaches and it took about a year for those to resolve. You saw that?

A Yes.

Q And you saw where Dr. Minkin actually referred to those as migraines? Did you see that?

A Yes.

Q In the context of what you've testified to earlier with regard to chronic pain as a contraindication and in the context of Dr. Benson's overall testimony, how does that fit in if, in fact, one were to consider that to be a chronic pain or

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or the results of her cystocele, is one of those results obstructed voiding?

A Yes.

Q And that was discussed by Dr. Raz as well during his testimony; correct?

A Yes.

Q And what is the obstructed voiding and why is that due to this recurrent prolapse that has occurred since all these surgeries had to be done after the Prolift®?

A What happens with a cystocele, when the bladder drops down, there's a kinking effect between the urethra and the bladder so that it becomes very difficult for the bladder to empty normally. And, in fact, Mrs. Wicker is in the very uncomfortable position of having to stand in order to be able to empty her bladder to try to overcome this obstructed voiding.

Q Do you believe as long as the cystocele is not able to be repaired that that will continue?

A Yes.

Q You were asked a question a moment ago about Linda Gross and whether her activities would be restricted by you. Remember that question?

A Yes.

migraine condition? How would that impact on your overall opinion?

A Yes. Well, as we discussed previously, what has been learned by surgeons over time is that patients with a preexisting pain condition are at much higher risk for either the exacerbation of their existing pain condition or the development of a new pain condition after the Prolift® procedure such that it is considered -- the Prolift® procedure is considered now contraindicated in those patients. So given the fact that Mrs. Gross has this history, then that would have served as a contraindication for her to undergo the Prolift® procedure at all.

Q With regard to a comparison of risks between certain native tissue repairs with sutures and the Prolift®, you were asked about various risks. Remember that mostly yesterday and a little today?

A Yes.

Q Is there a significant difference between the severity, the duration, and the treatability of pain with intercourse or discomfort with intercourse that a woman might experience after a native tissue repair as compared to the dyspareunia that a woman could suffer following a Prolift®?

Page 378 A Yes. There -that context; correct? 1 1 2 Q I don't need you to explain. I just want 2 Α Yes. 3 3 to establish that. You were asked about the summary of 4 4 medical records that was provided to you by my A Okay. 5 5 Q Counsel obviously can ask you about it, office and I think you said one or more deposition but I just want to make sure it's clear. I know 6 summaries. Ultimately, beyond just using those as a 6 7 it's explained in your report. 7 short summary of what had been provided just to get 8 Earlier in the deposition you testified 8 an idea of what was there, did you ultimately read each of the records yourself and read each of the 9 with regard to what you termed as Ethicon's 9 depositions yourself and rely on your own reading of 10 deception to surgeons at the time that Linda Gross 10 11 and Pam Wicker had the procedure. Remember that 11 the source materials to form your opinions? 12 testimony? 12 Α Yes. MR. SLATER: I have no other 13 A Yes. 13 14 O And in the course of your reports, did you 14 questions. detail your evaluation of the different things that BY MS. JONES: 15 15 you would term Ethicon's deception of surgeons Q Let me follow up just briefly, Doctor. 16 16 beginning with the launch up through those You were asked about dyspareunia following the use 17 17 18 surgeries? 18 of transvaginal mesh. Have you actually treated a woman who has had transvaginal mesh implanted for 19 19 A Yes. 20 20 prolapse for dyspareunia? Q One thing that you talked about was the failure of Ethicon to obtain 510(k) clearance. Are 21 A No. 21 22 there other aspects to Ethicon's deception beyond 22 You were asked about the obstructed their failure to tell doctors that the product had voiding that you say Ms. Wicker is experiencing? 23 23 not been cleared by the FDA? 24 Yes. 24 Α 25 A Yes. 25 Q Is that something that could be treated Page 379 1 Q You talked earlier in the deposition about 1 with the use of a Burch procedure? 2 2 your reliance on certain physicians with regard to MR. SLATER: You're asking the fact that the Prolift® mesh can harbor a chronic 3 3 specifically in Pam Wicker as things stand now? low-grade infection which can cause recurrent THE WITNESS: The Burch 4 4 5 erosions and other harm to a woman. Remember that 5 colposuspension is indicated for the treatment of 6 testimony? stress incontinence. It is not indicated to resolve 6 7 7 A Yes. obstructed voiding. 8 8 And you said that two of the physicians BY MS. JONES: you relied on were Dr. Raz and you referred to the 9 Q Do you know whether or not the use of that 10 doctor from Connecticut. That would be 10 procedure could be used for obstructed voiding in Dr. Kreutzer? Ms. Wicker? 11 11 12 A Yes. 12 A Well, of course, it could be. I wouldn't 13 Q Did you also rely on the opinions and 13 recommend it. experience of Dr. Margolis as well in that regard? Q Do you know whether or not the TVT® 14 14 15 15 procedure is available for use in obstructed You were asked if you had spoken with any voiding? 16 16 Prolift® users about the Prolift® or the Prolift® 17 17 A No. 18 professional education. Do you remember that? 18 MS. JONES: That's all I have. 19 Α 19 BY MR. SLATER: 20 You did, in fact, have the ability and you 20 Q Just to follow up on those last two did actually read the depositions of Dr. Benson, 21 questions, when you said Burch could be used, were 21 Dr. Bercik, Dr. Raders, Dr. Hinoul, Dr. Robinson, you saving that you would recommend it or think it's 22 22 Dr. Kirkemo, Dr. Jafri from the Firman case, you had an appropriate treatment for Pam Wicker? 23 23

A No. I was just responding in the general

sense that anybody can do anything, but I would not

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the opportunity to read extensive deposition

testimony from multiple users of the Prolift® in

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	Page 382			Page 384
1	recommend it.	1	TNICT	RUCTIONS TO WITNESS
1			IIVST	RUCTIONS TO WITHLSS
2	Q The problems that Dr. Raz testified with	2		
3	regard to during his trial testimony, those would	3	Please i	read your deposition over carefully
4	apply to any effort to treat the cystocele at this	4		necessary corrections. You should
5	point; correct?	5		on in the appropriate space on the
6	A Yes.	6	errata sheet fo	or any corrections that are made.
7	MR. SLATER: No other questions.	7	After do	ping so, please sign the errata
8	(Witness excused.)	8	sheet and date	
9	(Whereupon the deposition adjourned	9		e signing same subject to the
10	at 4:47 p.m.)	10	changes you h	ave noted on the errata sheet, which
11		11		d to your deposition.
		12		•
12				perative that you return the
13		13	original errata	sheet to the deposing attorney
14		14	within thirty (3	30) days of receipt of the deposition
15		15		ou. If you fail to do so, the
16		16		nscript may be deemed to be accurate
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		Page 386
1 2	ACKNOWLEDGMENT OF DEPONENT	
3 4 5 6 7 8 9 10 11 12	I, ANNE M. WEBER, M.D., M.S., do hereby certify that I have read the foregoing pages, 213-385, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.	
13 14 15 16	ANNE M. WEBER, M.D., M.S. DATE	
17 18 19 20	Subscribed and sworn to before me this, 2012. My commission expires:	
21 22 23 24 25	Notary Public	
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	LAWYER'S NOTES PAGE LINE	
19 20 21 22 23 24 25		